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OVERVIEW

Who we are

Established in 2019, we are a biopharmaceutical company focused on discovering and developing gene therapies for neurological and ophthalmic diseases. Our pipeline also includes oligonucleotide-based therapeutics. We have internally developed two Core Products, EXG102-031 and EXG001-307 (SMA Type 1), one Key Product, EXG202, and built a pipeline of six product candidates with our fully-integrated in-house R&D platform.

Our Core Product candidate, EXG102-031 is an adeno-associated virus (AAV)-based gene therapy for the treatment of wet age-related macular degeneration (wAMD), a severe form of AMD characterized by choroidal neovascularization. The other Core Product candidate, EXG001-307 (SMA Type 1), is a differentiated product for the treatment of spinal muscular atrophy (SMA) type 1 as well as the first domestically developed gene therapy for SMA in China to enter the registrational clinical trial stage, according to Frost & Sullivan. Our Key Product candidate, EXG202, is an AAV-based gene therapy for the treatment of fundus neovascularization diseases including wAMD, diabetic macular edema (DME) and retinal vein occlusion (RVO). According to Frost & Sullivan, EXG102-031 and EXG202 are the first and only gene therapies globally that simultaneously inhibits all key angiogenic pathways (VEGF A/B, VEGF-C/D, PlGF, and Angiopoietin-2). In addition, we are developing oligonucleotide-based therapeutics within our pipeline as well.

Our focused therapeutic technology

Gene therapy

Gene therapy refers to a method that uses delivery vectors to transduce normal or therapeutic exogenous genes into target cells, thereby replacing or correcting disease-causing genes. It treats the root cause of genetic diseases by fixing disease-causing genes and often works with a single dose and achieves long-lasting effects. According to Frost & Sullivan, the global gene therapy market is ushering in a period of rapid growth and is expected to grow from US\$3.6 billion in 2025 to US\$12.5 billion in 2030 with a CAGR of 28.3%, and further grow to US\$32.0 billion in 2035, representing a CAGR of 20.7% from 2030 to 2035.

The technological evolution of viral vectors for gene therapy has advanced from integrating lentiviral vectors, to broad-spectrum but target-limited wild-type AAV vectors, and now to AAV vectors engineered for precise targeting and enhanced safety. Building on advances in AAV-based gene therapy, we are developing product candidates that progress from genetic rare diseases toward prevalent conditions with unmet needs. Our pipeline includes two Core Product candidates for spinal muscular atrophy (SMA) and wet Age-related Macular Degeneration (wAMD), respectively, and a Key Product candidate for fundus neovascularization diseases, and additional assets targeting neurological and ophthalmic disorders.

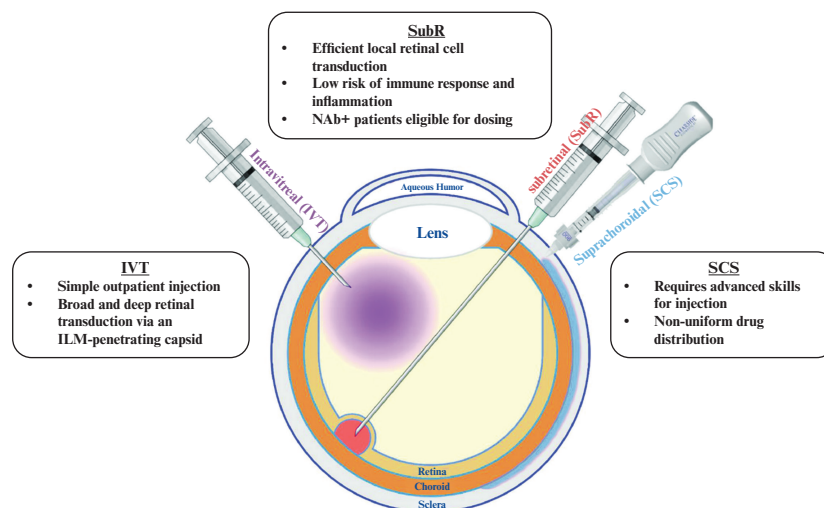
Fundus Neovascularization Disease

Fundus neovascularization disease refers to a group of eye disorders that affect vision due to pathological changes in the back of the eye, such as hemorrhage, exudation, and hyperplasia caused by excessive VEGF, which triggers abnormal blood vessel growth at the back of the eye. Major fundus neovascularization diseases include wAMD, DME and RVO. Globally, the fundus neovascularization disease drug therapy market is estimated to grow from US\$17.9 billion in 2025 to US\$30.7 billion in 2030 and US\$55.8 billion in 2035, and the estimated number of fundus neovascularization disease patients is expected to rise from 85.1 million patients in 2025 to 91.9 million by 2030 and 99.0 million by 2035, and the estimated number of wAMD patients is projected to rise from 21.6 million in 2025 to 23.7 million by 2030 and 25.7 million by 2035, according to Frost & Sullivan.

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The inhibition of angiogenesis with VEGF inhibitors is the first-line treatment for fundus neovascularization diseases. Current anti-VEGF treatments primarily inhibit single target pathway, however, incomplete inhibition can trigger compensatory increases in other angiogenic factors, contributing to persistent or recurrent disease activity and reduced therapeutic durability. Our Core Product candidate, EXG102-031, and our Key Product candidate, EXG202, are two distinct adeno-associated virus (AAV)-based gene therapies, designed to address current limitations for the treatment of fundus neovascularization diseases by delivering long-lasting, broad-spectrum angiogenesis inhibition to achieve synergistic and efficacy.

Gene therapy for fundus neovascularization diseases can be delivered through different injection routes, including (i) intravitreal (IVT) injection, where the treatment is injected into the vitreous, the gel-like center of the eye; (ii) subretinal (SubR) injection, in which the gene therapy product is delivered underneath the retina into the subretinal space, allowing for direct targeting of retinal and RPE cells; and (iii) suprachoroidal (SCS) injection, where the therapy is placed between the choroid and sclera. The following diagram illustrates the comparison of these three injection methods:



EXG102-031, is a one-time, subretinal-administered AAV-based gene therapy for the treatment of wAMD. According to Frost & Sullivan, subretinal injection, by delivering therapeutic agents directly to the subretinal space, enables precise targeting of the retinal pigment epithelium and photoreceptors, which are the key sites of disease pathology, thus enhancing treatment efficacy. The immune-privileged nature of the subretinal space offers a dual benefit: it improves the safety profile by reducing immune-related risks and inflammation, while also potentially enabling treatment in patients with pre-existing neutralizing antibodies — a common barrier to efficacy and eligibility in systemic AAV gene therapy.

EXG202 is a one-time, IVT-administered AAV-based gene therapy for the treatment of fundus neovascularization disease. According to Frost & Sullivan, IVT offers the strongest clinical scalability and implementation convenience. It is a well-established outpatient procedure that minimizes clinical complexity, and enables gene therapy to truly achieve large-scale commercialization potential. Meanwhile, it requires less specialized surgical skill, which lowers procedural risk, reduces cost, and improves patient access. With technological advancements, the transduction efficiency of IVT in the outer retina is significantly improving, further solidifying its strategic position as the most accessible and scalable route. Intravitreal injection is a well-established outpatient procedure that minimizes clinical complexity.

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SMA

SMA is an autosomal recessive lower motor neuron disease, characterized by progressive proximal muscle weakness and skeletal muscle atrophy. According to Frost & Sullivan, the global SMA drug therapy market is estimated to grow from US\$4,736.5 million in 2025 to US\$5,931.9 million in 2030 and US\$9,446.9 million in 2035, and the estimated number of SMA patients globally is expected to rise from approximately 176.9 thousand in 2025 to 195.5 thousand by 2030 and 210.8 thousand by 2035.

Approved treatments of SMA face limitations: poor adherence, insufficient neuronal SMN targeting and high costs. EXG001-307 (SMA Type 1) is a single-dose, AAV-based gene therapy designed to enable durable therapeutic expression of SMN. A key feature is its proprietary promoter, which directs expression within the central nervous system and minimizes it in peripheral tissues, thereby addressing a major safety limitation of current gene therapies. Furthermore, advances in manufacturing processes and know-how have significantly increased AAV production yields, leading to a reduction in overall costs. Consequently, the development of EXG001-307 (SMA Type 1) comprehensively addresses critical gaps in current SMA gene therapy approaches.

Oligonucleotide-based drugs

Oligonucleotides are a class of single- or double-stranded small synthetic nucleic acid polymers (≈ 20 -mer) that can be used to modulate gene expression, oligonucleotide-based drugs represent a class of therapeutics that target disease-related RNA at the molecular level, offering sequence-specific precision in modulating gene expression. The global oligonucleotide drug market increased from US\$3.0 billion in 2020 to US\$7.9 billion in 2025 at a CAGR of 21.7%, and is projected to reach US\$29.0 billion and US\$65.0 billion by 2030 and 2035, respectively, representing a CAGR of 29.7% and 17.5%, according to Frost & Sullivan.

Major oligonucleotides include siRNA, ASO, Aptamer and AOCs. The benefits of oligonucleotide-based drugs include high target specificity, long-lasting effect and platform technology advantage. Our oligonucleotide pipeline is strategically designed for high-impact diseases where traditional drugs fall short: EXG112 targets chronic pain and EXG115 targets Alzheimer’s disease.

Our product pipeline

Building on our expertise in rare genetic diseases, our strategic focus now encompasses the development of therapeutics for prevalent and high-burden diseases, such as fundus neovascularization diseases, chronic pain and Alzheimer’s disease, distinguishing ourselves from many peers that primarily target ultra-rare conditions, according to Frost & Sullivan.

We advance innovation across two cutting-edge fields in our R&D efforts and future product pipeline development: gene therapy and oligonucleotide-based therapeutics.

In the field of gene therapy, our Core Products and Key Product candidates have made significant progress in the development of treatments for SMA and fundus neovascularization diseases (wAMD/DME/RVO). In addition, we have further expanded our advanced gene therapy programs to include prevalent ophthalmic diseases such as dry AMD disease. In the field of oligonucleotide-based therapeutics, we are developing oligonucleotide-based therapies, with candidate drugs targeting chronic pain or Alzheimer’s disease now entering systematic development.

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Product	Indications	Target	Route of Administration	Monotherapy or combination therapy	Trial Locations	Line of Treatment	Self-developed, Licensed-in	Developmental Stage			Expected Upcoming Milestone	Jurisdictions
								IND & IND Preparation	Phase I	Phase II		
★ EXG102-031	wAMD	VEGF/PICP/ Ang2	SubR	Monotherapy	China, USA	Aflibercept, Bevacizumab, Brinzolizumab, Farnesinib-bisoxa, Ranibizumab, Conbercept	Self-developed	🟡	🟡	FDA and NMPA	2026H2 Phase III start	China, USA
🌟 EXG202	wAMD							🟡	🟡	FDA and NMPA	2026H2 Phase III start	China, USA
	DME	VEGF/PICP/ Ang2	IVT	Monotherapy	China	Aflibercept, Bevacizumab, Brinzolizumab, Farnesinib-bisoxa, Ranibizumab, Conbercept	Self-developed	🟡	🟡	FDA and NMPA	2027H1 Phase II start	China, USA
	RVO							🟡	🟡		2027H2 Phase II start	China, USA
EXG113	dry AMD	Complement factors	IVT	Monotherapy	China	Pegcetacoplan and Avacincaptal pegal	Self-developed	🟡			IND submission TBD	China, USA
★ EXG001-307	SMA Type 1	SMN1	IV	Monotherapy	China	Nusinersen, Onasemnogene adegaprovace (Zolgensma®), ITIVISMA®), Riidplum	Self-developed	🟡	🟡	NMPA	2026H2 Phase III regulatory alignment	China, USA, Europe, Japan
EXG112	Chronic Pain	Nar 1/7	IT	Monotherapy	China	NSADs, acetaminophen, anticonvulsants, opioids	Self-developed	🟡	🟡		2027H1 IT start, 2028H1 IND submission	China, USA
EXG115	Alzheimer's Disease	Tau	IV or SubQ	Monotherapy	China	Arcetep, Exelon, Razadyne, Namenda, Leqembi and Kisunla	Self-developed	🟡	🟡		IND submission TBD	China, USA
EXG116	Reti Syndrome	MECP2	IV or IT	Monotherapy	China	Trofistide	Self-developed	🟡			2028H2 ITT	China, USA
EXG110	Fibry Disease	GLA	IV	Monotherapy	China	Fibrzyme, Galafold, Ellfibrio	Self-developed	🟡	🟡	NMPA	2028H2 Phase Completion	China, USA
EXG111	DMD	Dystrophin	IV	Monotherapy	China	Enflunaz, Agamree, Exondys 51, Vyondys 53, Vileproq, Amondys 45, Elevidys	Self-developed	🟡			2029H2 IND submission	China, USA
★ Core Products	SMA: Spinal Muscular Atrophy			DME: Diabetic Macular Edema	DMD: Duchenne Muscular Dystrophy	IV: Intravenous Injection	SubR: Subretinal Injection	IND Investigational New Drug				
★ Key Product	wAMD: wet Age-related Macular Degeneration			RVO: Retinal Vain Occlusion	IT: Intrathecal Injection	IVT: Intravitreal Injection	ITT: Investigator Initiated Trial	SubQ: Subcutaneous Injection				

Notes:

- (1) EXG202 for DME/RVO plans to engage with the NMPA to progress directly to Phase II, supported by wAMD data.
- (2) VEGF includes VEGF-A, -B, -C and -D
- (3) Abbreviations: H1 = first half; H2 = second half; TBD = to be determined

Our platforms

Our platforms provide distinct advantages in precision, efficiency, and translational potential, enabling the accelerated development of safe and effective gene therapies and oligonucleotide-based therapeutics.

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We have established a dual technology platform system consisting of *AAVarta* and *SODA* that covers the two core aspects of gene therapy: “precise delivery” and “gene regulation”. Precise and efficient delivery is fundamental to the success of any therapeutic and is particularly critical in gene therapy, where clinical efficacy is largely determined by vector performance. A key limitation of current gene therapies is the lack of capsids capable of targeting disease-relevant organs and tissues efficiently and selectively. To address this challenge, we have developed *AAVarta*, a proprietary, AI-assisted platform designed to discover and optimize gene delivery vectors. Through iterative data integration and model refinement, *AAVarta* has generated novel capsids with transduction of retinal tissues, enhanced muscle targeting, and capsids capable of efficiently bypassing the blood-brain barrier (BBB). The BBB-penetrating capsids achieved broad neuronal transduction in the central nervous system, with up to a 200-fold increase in efficiency compared with wild-type AAV capsids.

The *SODA* platform is a validated gene-silencing design and optimization engine dedicated to the development of oligonucleotide-based therapeutics and modulatory gene therapy. *SODA* integrates target biology assessment, bioinformatics-driven sequence selection, chemical modification strategies, and high-throughput functional screening to generate oligonucleotide candidates with high specificity, potent and durable gene silencing, and minimized off-target effects. The platform supports multiple oligonucleotide and gene therapy modalities, including ASO, siRNA, miRNA, antibody-oligonucleotide conjugates (AOC). In addition, *SODA* platform also supports the design of optimized gene therapy constructs to achieve precise modulation of target genes. It systematically advances candidates from rational design through preclinical validation, enabling efficient translation toward clinical development.

Collectively, the *AAVarta* and *SODA* platforms operate in close collaboration, synergizing expertise across gene therapy vector design, oligonucleotide engineering, and sequence optimization for efficient *in vivo* delivery. Together, they form the integrated technological backbone for a new generation of therapies, combining maximized efficacy, safety, and versatility across both modalities.

OUR COMPETITIVE STRENGTHS

The first and only ophthalmic gene therapy in the world targeting all key angiogenic pathways (VEGF A/B, VEGF-C/D, PlGF, and Ang2)

Fundus neovascularization is driven by multiple angiogenic pathways. Compensatory signaling and bypass activation contribute to suboptimal or non-durable responses to anti-VEGF monotherapy, highlighting the need for next-generation therapies that target multiple angiogenic mechanisms. According to Frost & Sullivan, our Core product EXG102-031 is the first gene therapy globally that simultaneously inhibits all key angiogenic pathways (VEGF A/B, VEGF-C/D, PlGF, and Ang2). Independently developed by us for the treatment of wet age-related macular degeneration (wAMD), EXG102-031 broadly suppresses vascular leakage and neovascularization at the root, enabling durable and comprehensive therapeutic benefits. As of the Latest Practicable Date, EXG102-031 has demonstrated excellent safety and significant efficacy following subretinal injections. For details, see “Business — Our Product Pipeline — EXG102-031 — Core Product Candidate — Competitive Advantage — Phase I/II Trial Status and Data” in this document. Compared with intravitreal injection products, subretinally administered EXG102-031 reduces immunogenic responses, circumvents limitations imposed by pre-existing neutralizing anti-AAV antibodies, and enables strong and reliable *in situ* retinal expression.

Building on the innovative mechanism of action and successful experience of EXG102-031, we are simultaneously advancing the clinical trials of EXG202 through intravitreal administration. Together, EXG102-031 and EXG202 represent the only gene therapy candidates globally designed to inhibit all key angiogenic pathways. Intravitreal injection is a non-surgical procedure, making it more accessible in routine clinical practice and enabling treatment of a broader patient population. EXG202 utilizes a novel, independently developed engineered AAV capsid that, following intravitreal injection, achieves broader retinal coverage and deeper tissue penetration. EXG202 has been generally

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well tolerated in the IIT and IND Phase I to date. For details, see “Business — Our Product Pipeline — EXG202 — Key Product Candidate — Competitive Advantage — Investigator Initiated Trial” in this document.

An innovator in SMA gene therapy, with differentiated product candidate in the world

Our Core Product, EXG001-307 (SMA Type 1), a recombinant adeno-associated virus (rAAV) gene therapy, is a differentiated product candidate for the treatment of SMA as well as the first domestically developed gene therapy for SMA in China to advance to registrational clinical trial stage, according to Frost & Sullivan. As of the Latest Practicable Date, we have completed Phase I/II clinical trials of EXG001-307 (SMA Type 1) and currently plan to initiate the discussion with the regulatory authority about the design for the Phase III clinical trial in 2026 H2.

A key innovation of EXG001-307 (SMA Type 1) is its neuron-preferential gene expression control. The construct incorporates a proprietary promoter that enables transgene expression in neurons, whereas reduces expression in peripheral organs such as the liver and heart, thereby mitigating systemic exposure and lowering the risk of dose-limiting toxicity. As an AAV gene therapy product, EXG001-307 (SMA Type 1) ensures stable, long-lasting expression of SMN protein, offering the potential for “one-time administration, long-term efficacy”, thereby significantly improving treatment efficacy and patient adherence.

Benefiting from the design of gene expression control, EXG001-307 (SMA Type 1) has demonstrated significant therapeutic advantages in clinical studies. For details, see “Business — Our Product Pipeline — EXG001-307 (SMA Type 1) — Our Core Product candidate — Competitive Advantage — SMA Type 1 Phase I/II Trial Status and Data” in this document. EXG001-307 (SMA Type 1) has demonstrated advantages over currently marketed therapies in achieving key motor milestones, which not only confirms its exceptional therapeutic potential, but also signals new hope for the SMA patient community.

AI-assisted, clinically validated vector design enabling well-performing gene therapy candidates

We have built an AI-assisted, innovative vector design platform that directly address the central determinant of gene therapy success: precise and efficient *in vivo* delivery. The platform has established a differentiated competitive advantage by enabling the discovery, optimization, and clinical translation of optimized AAV vectors. In addition to novel capsid design and development, AI-assisted platforms have also been applied to vector payload optimization, including promoter engineering and transgene sequence optimization, resulting in novel designs incorporated into our Core Products EXG102-031 and EXG001-307, our Key Product EXG202, and the clinical-stage pipeline candidate EXG110.

AAVarta integrates deep-learning algorithmic design, protein structure prediction and new binder generation, high-throughput screening, and iterative wet-lab validation in an end-to-end workflow to generate novel AAV capsids with enhanced tissue tropism and delivery properties. For details, see “Business — Research and Development — Our Platforms”.

The platform has successfully generated multiple validated capsids, demonstrating its broad utility across retinal, muscular, and CNS diseases.

Developing oligonucleotide therapeutics for prevalent diseases

Our oligonucleotide therapeutics portfolio is enabled by *SODA* platform that supports the rational creation and translational advancement of oligonucleotide-based medicines and modulatory gene therapies. *SODA* integrates bioinformatics-driven sequence selection, chemical modification strategies, and high-throughput *in vitro* screening to systematically design antisense oligonucleotide (ASO), small interfering RNA (siRNA), microRNA (miRNA), and antibody oligonucleotide conjugate (AOC) candidates. Our company leverages this platform to develop oligonucleotide therapeutics for prevalent diseases with significant unmet needs.

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SODA platform has the ability to generate oligonucleotide therapeutics with predictable, consistent performance across multiple modalities, including ASO, siRNA, RNAi, and AOC. Together, these capabilities underscore *SODA*’s dual role: a clinically oriented engine powering gene-silencing therapeutics, and a foundational platform driving the development of translatable RNAi medicines for highly prevalent, underserved diseases. For details, see “Business — Research and Development — Our Platforms”.

Solid manufacturing process in the gene therapy industry

Manufacturing process development and the associated know-how are distinct from manufacturing operations themselves. Leveraging our proprietary technologies and patented techniques, we are able to transfer our processes to third-party CDMOs to enable efficient, high-yield AAV manufacturing. We have established a solid gene therapy manufacturing process based on large-scale HEK293 cell suspension culture system. This manufacturing process is built on proprietary patented technologies, delivering outstanding production efficiency and scalability while ensuring consistent and controllable product quality. For details, see “Business — MANUFACTURING — Our Manufacturing Process” in this document.

Leveraging advanced process analytical technologies and a rigorous quality control system, our production process ensures high consistency and long-term controllability of critical quality attributes. This technologically reliable manufacturing process not only provides a solid foundation for the industrialization and quality assurance of our products, but also represents a core technical advantage that underpins our continued leadership and advancement in the field of gene therapy.

Capable and experienced senior management team

We are led by a mature, visionary, and internationally oriented senior management team that oversees all core business areas, including product design, platform development, clinical research, strategic planning, and commercial partnerships. Our management team members have an average of over 20 years of professional experience in the biopharmaceutical industry. Their deep expertise, comprehensive understanding of disease pathophysiology across multiple therapeutic areas, and outstanding leadership capabilities are key drivers behind our ability to build a diversified gene therapy pipeline, advance toward successful commercialization, and maintain a strong competitive edge. For details, see “Directors and Senior Management” in this document.

OUR BUSINESS STRATEGIES

We pursue a globally oriented, platform-enabled commercialization strategy designed to translate breakthrough science into safe, durable, and accessible gene and oligonucleotide therapies for diseases with significant unmet medical need and substantial market potential. While our development originated in rare inherited disorders, we are strategically expanding toward high-burden, large-population indications across ophthalmology and neurology, diseases, positioning our portfolio for both clinical impact and long-term commercial scale.

Advance differentiated therapies with global development pathways

Across our Core and Key Products, we focus on accelerating clinical development through parallel, multi-regional trials, particularly in China and the United States, to enable synchronized global registrations and shorten time to market. By integrating shared clinical, regulatory, and operational frameworks, we maximize efficiency, ensure data interoperability, and support mutual regulatory recognition, strengthening our ability to establish potentially first- positions in competitive therapeutic landscapes.

For our Core Product, EXG102-031, we plan to initiate the Phase IIb/III trial in 2026 H2 in China. For the other Core Product, EXG001-307 (SMA Type 1), we plan to initiate the discussion with the regulatory authority for the pivotal Phase III trial design in 2026 H2. For our Key Product, we intend to initiate the Phase IIb trial in 2026 H2. For detailed implementation plans and allocated [REDACTED], see “Future Plans and [REDACTED]” of this document. To support commercialization of our Core and Key Products, we will adopt a hybrid strategy combining independent operations and collaborations with biopharmaceutical companies via strategic partnerships.

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Accelerate platform-driven expansion into highly prevalent diseases

Underlying our strategy is the continuous evolution of our AI-enabled *AAVarta* and *SODA* platforms, which drive rapid iteration, pipeline expansion, and high translational success rates. These platforms enable a repeatable development engine, from discovery to clinic. This enables us to expand into additional high-value indications with larger patient populations and high unmet medical needs. Combined with disciplined project management, cross-regional execution, and strategic partnerships, we are building a dual-engine growth model powered by internal innovation and external collaboration. For detailed implementation plans and allocated [REDACTED], see “Future Plans and [REDACTED]” of this document.

Deliver superior safety, durability, and patient convenience

Our product design philosophy emphasizes long-term efficacy, favorable safety profiles, and patient-centric delivery. By integrating advanced capsid engineering, payload optimization, and multi-mechanism therapeutic strategies, our programs aim to reduce treatment burden, enhance durability, increase patient adherence, and improve real-world outcomes, supporting the transition of gene therapy from an emerging option to a mainstream standard of care in selected indications.

Build scalable, high-quality, and cost-efficient manufacturing process

Manufacturing process development and the associated know-how are distinct from manufacturing operations themselves. Leveraging our proprietary technologies and patented techniques, we are able to transfer our processes to third-party CDMOs to enable efficient, high-yield AAV manufacturing. We are establishing a scalable CMC and manufacturing process capable of supporting both late-stage clinical development and commercial supply. Through process scale-up and automation, we aim to enhance yield, purity, consistency, and product quality while continuously reducing cost of goods. This manufacturing strategy supports our commitment to affordable and broadly accessible gene therapies, a critical differentiator as the company and field moves toward larger patient populations and real-world adoption.

Drive commercial readiness and global market access

Commercial execution is advanced in parallel with late-stage development. We are building a forward-looking commercialization system encompassing medical affairs, physician education, surgical and administration training, supply chain readiness, and market access planning. Flexible go-to-market models, including independent commercialization, regional partnerships, and licensing, allow us to efficiently penetrate global markets while managing risk and capital allocation.

OUR PRODUCT PIPELINE

Overview

Since our inception, we have adopted and executed our strategic business model of self-developing differentiated biopharmaceutical products with a focus on gene therapies. Among our pipeline, our Core Product candidate, EXG102-031, is for the treatment of wAMD. The other Core Product candidate, EXG001-307 (SMA Type 1), is for the treatment of SMA. In addition to our Core Product candidates, we are also developing one key product candidate, EXG202, is for the treatment of fundus neovascularization. Our pipeline also includes oligonucleotide-based therapeutics. The following chart summarizes our pipeline spanning ophthalmic, neurological, and other diseases, and the development status of each product candidate as of the Latest Practicable Date. Our product candidates are discovered and developed in-house, and we own global rights over our product candidates.

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EXG102-031 - Core Product Candidate

Overview

EXG102-031 is an adeno-associated virus (AAV)-based gene therapy product candidate for the treatment of wet age-related macular degeneration (wAMD), a severe form of AMD characterized by fundus neovascularization. EXG102-031 is injected directly into the immune-privileged subretinal space via subretinal injection, and transduces retinal pigment epithelium (RPE) cells and photoreceptors, delivering a transgene encoding a proprietary multi-target anti-angiogenic fusion protein, while avoiding exposure to pre-existing neutralizing antibodies in the vitreous.

Once expressed, this fusion protein inhibits all key angiogenic pathways (VEGF-A/B, VEGF-C/D, placental growth factor (PlGF), and Angiopoietin-2 (Ang2)), thereby suppressing multiple angiogenic pathways implicated in fundus neovascularization. EXG102-031, together with our Key Product candidate, EXG202, collectively represents the first and only ophthalmic gene therapy programs designed to comprehensively target this all the key angiogenic pathways. This coordinated, multi-pathway inhibition represents a differentiated therapeutic approach, as no approved therapies and investigational candidates target this broad spectrum of angiogenic drivers. By supporting sustained intraocular expression following a single subretinal administration, EXG102-031 provides durable control of neovascular growth, vascular leakage and retinal edema while substantially reducing reliance on frequent intravitreal anti-VEGF injections and associated real-world treatment burdens.

EXG102-031 received IND approval from the FDA in January 2023 and from the NMPA in June 2023. As of the Latest Practicable Date, the Phase I/II clinical trial of EXG102-031 had completed enrollment at 10 clinical sites (2 in the United States and 8 in China). A total of 39 patients were treated across five dose cohorts in China and four dose cohorts in the U.S. in the Phase I stage and two cohorts in the Phase IIa dose-expansion. Both the Phase I and Phase IIa stages have completed the last visit (52-week) in the main study, and the long-term follow-up is ongoing.

Interim results demonstrated clinically meaningful improvements in both visual acuity and anatomical outcomes, along with a substantial reduction in treatment burden. BCVA and CRT were consistently maintained or improved through 12 months of follow-up across cohorts. EXG102-031 was generally well tolerated, with no treatment-related serious adverse events (SAE), no dose-limiting toxicities (DLT), and no severe ocular complications.

In China trials, all enrolled patients in the Phase IIa have completed the 52-week visit, the final visit in the main study. The Phase IIb/III trial is expected to commence in the second half of 2026. In the United States, Phase I clinical trial of EXG102-031 has been completed and the clinical database has been locked since March 20, 2026.

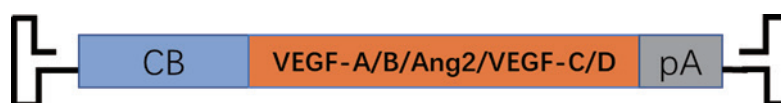
Mechanism of Action

wAMD is driven by dysregulated angiogenesis involving multiple VEGF signaling pathways and the destabilizing effects of Ang2. VEGF-A, VEGF-B, VEGF-C, VEGF-D and PlGF promote neovascular proliferation and vascular leakage through VEGFR1, VEGFR2 and VEGFR3, while Ang2 synergistically increases vascular permeability and destabilizes endothelial junctions. Current pharmacologic therapies primarily inhibit VEGF-A alone, or in the case of dual-targeting agents, VEGF-A and Ang2. However, incomplete inhibition can trigger compensatory increases in VEGF-C, VEGF-D and Ang2, contributing to persistent or recurrent disease activity and reduced therapeutic durability.

EXG102-031 is a recombinant AAV vector delivered via subretinal injection, placing the vector within the immune-privileged subretinal space. Compared with alternative delivery routes such as suprachoroidal (SCS) or intravitreal administration, subretinal delivery enables more efficient and localized transduction of retinal pigment epithelium (RPE) cells and photoreceptors while minimizing exposure to pre-existing neutralizing antibodies present in the vitreous or choroidal circulation, thereby leveraging the immune-privileged subretinal environment to reduce immune activation and intraocular inflammation and support a more favorable safety profile.

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EXG102-031: AAV construct design



EXG102-031 (rAAV2)

Source: Company diagram.

Following subretinal injection of EXG102-031, transduced RPE cells and photoreceptor cells express a proprietary multi-target anti-angiogenic fusion protein containing the ligand-binding domains of VEGFR1, VEGFR2 and VEGFR3 together with an Ang2-binding domain. This novel approach enables coordinated inhibition of VEGF-A/B, VEGF-C/D, PlGF, and Ang2, as summarized in the Table below which provides a side-by-side overview of angiogenic pathway coverage among selected AAV-based gene therapies. This comprehensive pathway suppression prevents compensatory signaling, overcomes incomplete response, and provides durable control of exudation, neovascular growth and edema.

Product	Targeted Pathways					
	VEGF-A	VEGF-B	VEGF-C	VEGF-D	PlGF	Ang-2
EXG102-031	✓	✓	✓	✓	✓	✓
EXG202	✓	✓	✓	✓	✓	✓
RGX-314 (ABBV/REGENXBIO)	✓					
4D-150 (4D Molecular Therapeutics)	✓	✓	✓ (Inhibition via miRNA)		✓	
Ixo-vec/ADVM-022 (Adverum)	✓	✓			✓	

Source: Literature Review, F&S Analysis

EXG102-031 represents the first ophthalmic gene therapy program designed to comprehensively target all the key angiogenic pathways. By enabling sustained and localized intraocular expression of this fusion protein, EXG102-031 is designed to mitigate compensatory signaling, provide durable disease control, reduce reliance on frequent intravitreal anti-VEGF injections in wAMD.

As a gene therapy drug candidate, the key components of EXG102-031, the function of each component, and ownership are shown in the table below:

Component	Function	Ownership
AAV2 wild type capsid	Vector used to deliver transgene to the target cells	The patent has expired and legally enters the public domain.

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Component	Function	Ownership
DNA construct expressing anti-angiogenic factors	To express a recombinant protein blocking all the key angiogenic pathways to treat wet AMD patients	The Company fully owns the patent of the construct design.

As advised by Zhonglun Law Firm, our intellectual property counsel, we confirm that we own the patents to the product EXG102-031 and the DNA construct listed above, while the full term of the patent on AAV2 wild type capsid has expired and such expired patent will not restrict our use of AAV2 wild type capsid in EXG102-031 or otherwise jeopardize the R&D and future commercialization of EXG102-031.

Given that the key differentiation of EXG102-031 from other comparable products currently on the market lies in the design of its payload, rather than the capsid, the expiration of AAV2 capsid patent protection and its entry into the public domain is not expected to adversely affect the market competitiveness of EXG102-031. Accordingly, even if we do not develop a novel capsid, we believe this would not impair the competitive position of EXG102-031.

Market Opportunity and Competition

Market Opportunity

Wet age-related macular degeneration (wAMD) is a prevalent and vision-threatening fundus neovascularization disease and a leading cause of irreversible blindness among older adults. In 2025, global wAMD prevalence reached 21.6 million, and is projected to rise to 23.7 million by 2030 and 25.7 million by 2035. In China, the wAMD population reached 4.0 million in 2025 and is expected to grow to 4.6 million by 2030 and 5.0 million by 2035.

Despite advances in anti-VEGF biologics, wAMD remains a chronic and recurrent disease with substantial unmet need. Approved therapies require frequent and long-term intravitreal injections, resulting in significant treatment burden and poor real-world adherence, with many patients receiving fewer injections than recommended or discontinuing therapy early. Even among treated patients, incomplete or non-durable disease control is common, with persistent fluid, progressive anatomical changes or vision decline, and relapse after treatment interruption. These limitations reflect both biological constraints, including incomplete suppression of angiogenic pathways and compensatory signaling, and practical challenges associated with repeated intravitreal administration.

Given the rising prevalence of wAMD, the aging global populations, the significant clinical and economic burden of disease and the limitations of existing anti-VEGF treatments, there is strong and growing market demand for safe, effective and accessible single-dose gene therapies.

Current Treatment Options and Limitations

As of the Latest Practicable Date, all approved pharmacologic therapies for wAMD are anti-VEGF biologics requiring repeated dosing. These include ranibizumab (Lucentis®), a monoclonal antibody fragment targeting VEGF-A; aflibercept (Eylea®) and conbercept (Lumitin®), which are VEGF-receptor-based fusion proteins that bind VEGF-A, VEGF-B and PlGF; and faricimab-svoa (Vabysmo®), a bispecific antibody targeting both VEGF-A and Ang2. These products have demonstrated clinical efficacy and remain the standard of care in major markets including the United States and China.

Despite these therapeutic advances, current anti-VEGF therapies face significant biological limitations. While some approved agents inhibit more than one ligand (e.g., Eylea® and Lumitin® also bind VEGF-B and PlGF, and Vabysmo® targets Ang2 in addition to VEGF-A), none provide comprehensive suppression of all the key angiogenic drivers

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implicated in wAMD. Incomplete inhibition of pathways involving VEGF-C, VEGF-D and Ang2 may allow compensatory signaling, contributing to persistent or recurrent disease activity and limited durability of response.

In addition, current therapies require frequent intravitreal injections and long-term maintenance, leading to poor real-world adherence. In China, patients receive an average of only 4.2 injections in the first year, declining to 2.8-3.5 injections annually thereafter, with a ten-year average of fewer than three injections per year, and approximately 80% of patients ultimately discontinue anti-VEGF therapy, nearly 50% within the first year.

Frequent intravitreal injections impose substantial physical and psychological burden and procedural risks, contributing to poor adherence, which is commonly reported below 50% and falls to less than 44% after one year in fundus neovascularization diseases. Even among patients who remain on therapy, 40-50% of treated exhibit persistent retinal fluid at 12–24 months, approximately 20% never achieve complete fluid resolution, macular atrophy occurs in ~11% of eyes at 12 months and 29% at 24 months, and ~30% of patients relapse within one year after treatment discontinuation, reflecting both biological pathway limitations and real-world adherence constraints.

Overall, existing anti-VEGF therapies are limited by narrow pathway coverage, limited durability, poor real-world adherence, frequent injections, long-term safety concerns and incomplete anatomical response, underscoring the need for new therapeutic modalities capable of sustained, multi-pathway suppression with fewer administrations. EXG102-031 is designed to address these unmet needs by providing long-lasting, broad-spectrum angiogenesis inhibition following a single subretinal administration.

Competitive Landscape

Anti-VEGF monoclonal antibodies and fusion proteins remain the standard of care for wet age-related macular degeneration (wAMD) and represent the primary competitors to EXG102-031 today. Approved products include Lucentis® (ranibizumab); Eylea® (aflibercept), Lumitin® (conbercept), and Vabysmo® (faricimab-svoa).

In parallel, several AAV-based gene therapies for wAMD are in clinical development. The most advanced include RGX-314 (REGENXBIO), an AAV8-based gene therapy delivered via subretinal injection and currently in Phase III development, and ADV-022 (Adverum Biotechnologies), an intravitreally administered AAV-based gene therapy in Phase III trials. A third global clinical-stage program, 4D-150 (4D Molecular Therapeutics), is an intravitreally delivered AAV-based gene therapy targeting VEGF-A, VEGF-B, VEGF-C and PlGF and has also progressed to Phase III development. As of the Latest Practicable Date, no gene therapy for wAMD has been approved in the United States, Europe, Japan or any other major market.

Global Competitive Landscape of Gene Therapy Pipelines for Treatment of wAMD

Drug Name/Code	Target	Company	Clinical Stage	Indication	First Posted Date
EXG102-031	VEGF-A/B/C/D, Ang2, PlGF	ExeGenesis Bio	Phase I/II	wAMD	2023/6/6
EXG202	VEGF-A/B/C/D, Ang2, PlGF	ExeGenesis Bio	Phase I/II	nAMD	2025/9/17
ABBV-RGX-314	VEGF	AbbVie	Phase II/III	nAMD	2021/1/12
Ixoberogene Soroparvovec.	VEGF	Adverum Biotechnologies	Phase III	nAMD	2025/3/4
4D-150.	VEGF-A/B/C, PlGF	4D Molecular Therapeutics	Phase III	nAMD	2025/3/7
NG101.	VEGF-A	Neuracle Genetic	Phase I/II	nAMD	2023/8/9
KH631.	VEGF	Kanghong Pharmaceutical	Phase I	nAMD	2022/12/10
KH658.	VEGF	Kanghong Pharmaceutical	Phase I	nAMD	2025/2/8

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Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past five years.

Source: Clinicaltrials.gov, Company website, Literature research, F&S Analysis

In China, the wAMD gene therapy landscape is expanding but remains at an early stage. Several international and domestic companies are developing AAV-based gene therapies, including LX102 (Innostellar Biotherapeutics), RRG001 (RRGene Therapeutics), SKG0106 (Skyline Therapeutics), XMVA09 (Starry Gene), AL-001 (Anlong Bio), JWK001 (Genevector), IVB103 (InnoVec Bio), FT-003 (Frontera Therapeutics), KH631 and KH658 (Kanghong Pharmaceutical), as summarized in the Table below.

China Competitive Landscape of Gene Therapy Pipelines for Treatment of wAMD

Drug Name/Code	Target	Company	Clinical Stage	Indication	First Posted Date
EXG102-031	VEGF-A/B/C/D, Ang2	Exegensis Bio	Phase I/II	wAMD	2023/10/12
EXG202	VEGF-A/B/C/D, Ang2	Exegensis Bio	Phase I/II	wAMD	2025/9/18
AL-001	VEGF	Anlong Bio	Phase II	wAMD	2025/2/18
HX9428.	VEGFR2	Fujian Haixi Pharmaceuticals	Phase II	wAMD	2026/7/30
LX102.	VEGF	Innostellar Biotherapeutics	Phase III	nAMD	2026/01/24
KH631.	VEGF	Kanghong Pharmaceutical	Phase I/II	nAMD	2023/2/2
FT-003.	VEGF	Frontera Therapeutics	Phase I/II	nAMD	2023/8/21
RRG001.	VEGF	RRGENER Therapeutics	Phase I/II	nAMD	2023/11/21
SKG0106	VEGF-A	Skyline Therapeutics	Phase I/II	nAMD	2023/12/27
XMVA09	Ang2, VEGF-A	Starry Gene	Phase I/II	wAMD	2024/4/12
JWK001	VEGF	Genevector	Phase I/II	nAMD	2024/5/30
KH658.	VEGF	Kanghong Pharmaceutical	Phase II	nAMD	2026/7/7
IVB103	NA	InnoVec Bio	Phase I/II	nAMD	2024/11/29
NGGT007.	NA	Next Generation Gene Therapeutics	Phase I/II	nAMD	2025/1/16
CRG-B191	VEGF	CorreGe	Phase I/II	wAMD	2025/11/6

Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past three years.

Source: CDE, Company website, Literature research, F&S Analysis

With the exception of RGX-314, ADVN-022 and 4D-150, the majority of these candidates remain in early-phase clinical or investigator-initiated trials. As of the Latest Practicable Date, no AAV-based gene therapy for wAMD had received marketing approval in China or overseas, and all candidates were still in clinical development.

Competitive Advantage

EXG102-031 expresses a multi-target fusion protein that simultaneously inhibits VEGF-A/B, VEGF-C/D, placental growth factor (PlGF) and angiopoietin-2 (Ang2), enabling broad suppression of angiogenic signaling and limiting compensatory pathway activation.

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Delivered via a single subretinal administration, EXG102-031 is designed to provide sustained intraocular expression, with the potential to provide long-lasting therapeutic effect, and substantially reduce treatment burden compared with therapies requiring repeated intravitreal dosing.

Subretinal delivery provides an additional and important advantage for EXG102-031. This route enables highly efficient AAV transduction in localized RPE and photoreceptor cells, and avoids the limitations associated with pre-existing neutralizing antibodies in the vitreous and reduces the risk of immune-mediated intraocular inflammation. This delivery approach supports durable expression of the therapeutic fusion protein from a single injection and is expected to significantly reduce reliance on frequent intravitreal injections.

Interim efficacy results from the Phase I/II clinical trial conducted in China and the United States further support the therapeutic potential of EXG102-031. As detailed in the following Table and the “Phase I/II Trial Status and Data” section below, across dose cohorts, patients demonstrated clinically meaningful improvements in best-corrected visual acuity (BCVA) and central retinal thickness (CRT), together with a marked reduction in the need for rescue anti-VEGF treatment. As summarized in the table below, these outcomes compare favorably across key durability and treatment-burden metrics relative to reported 6-month results from other clinical-stage AAV-based anti-VEGF gene therapies, based on publicly disclosed trial data.

6-Month Clinical Outcomes of Anti-VEGF Gene Therapies

Company/ Product	Targets	Dosing Routes [#]	Dose (vg/eye)*	BCVA improvement (letters)	CRT Reduction (µm)	% Injection- Free Patient	% Annualized anti-VEGF Reduction
ExeGenesis Bio/ EXG102-031	VEGF-A/B/C/D, PIGF, Ang2	SR	1.8 x 10 ¹¹ (n=12)	+6.2	-91.5	92%	-97%
REGENXBIO/ RGX-314	VEGF-A	SR	6.4 x 10 ¹⁰ (n=15)	+2.9	-5.5	73%	-68%
			1.3 x 10 ¹¹ (n=15)	+8.6	-12.6	60%	-68%
Adverum/ ADVM-022	VEGF-A/B, PIGF	IVT	6 x 10 ¹⁰ (n=30)	-1.1	-12.6	76%	-90%
4DMT/ 4D-150	VEGF-A/B/C, PIGF	IVT	3 x 10 ¹⁰ (n=30)	+3.5	-9.2	77%	-89%

Note: These results were obtained from different trials and are not based on a head-to-head comparison.

For comparison with EXG102-031, we selected only Phase III gene therapies, using their available 6-month data from Phase II trials.

[#] Dosing routes: IVT=intravitreal injection; SR=Subretinal injection

^{*} Doses advanced to Phase III trials

Source: F&S Analysis

EXG102-031 was generally well tolerated, with no treatment-related serious adverse events, no dose-limiting toxicities and no severe ocular complications such as endophthalmitis, retinal detachment or irreversible vision loss reported as of the Latest Practicable Date.

Phase III Clinical Trial in China

Overview. We are conducting a combined Phase I/II clinical trial of EXG102-031 (EXG102-031-111) in China to evaluate its safety, tolerability and preliminary efficacy in patients with wet age-related macular degeneration (wAMD). The Phase I clinical trial adopts a dose-escalation design to assess the safety and tolerability of ascending dose levels. Based on the Phase I safety and efficacy data, recommended doses will be selected for expansion in the Phase II clinical trial. According to the clinical protocol, progression from dose escalation (Phase I) to dose expansion (Phase II) does not require additional regulatory approval from the NMPA. Instead, advancement to Phase II clinical trial only requires review by an

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independent Data and Safety Monitoring Board (DSMB). On August 19, 2024, the DSMB approved progression to the Phase II expansion phase.

Trial Design. The Phase I portion of study in China follows an open-label, multi-center, single-dose, 3+3 dose-escalation design. Patients receive a single subretinal injection of EXG102-031 at ascending dose levels of 2.0×10^{10} , 4.0×10^{10} , 1.0×10^{11} , 1.8×10^{11} and 2.5×10^{11} vg/eye. Dose escalation proceeds following safety review of each cohort. The Phase II stage includes two Recommended Phase II Dose (RP2D) cohorts (1.0×10^{11} and 1.8×10^{11} vg/eye), enrolling approximately 3–9 subjects per group, to further evaluate safety, tolerability and potential efficacy.

The key inclusion criteria for the study included but not limited to: a clinically meaningful response to standard anti-VEGF therapy within six months prior to screening or during the screening run-in period. In addition, the study eye must be pseudophakic (post-cataract surgery), with intraocular lens implantation having occurred at least one month prior to enrollment.

The key exclusion criteria included but not limited to: (1) the presence in the study eye of any ocular disease other than wAMD that may affect central vision and/or macular assessments; (2) MNV due to causes other than wAMD in the study eye, or a history of macular pathology unrelated to wAMD; (3) structural retinal damage involving the fovea; (4) subretinal hemorrhage involving the foveal center in the study eye with a hemorrhage area ≥ 4 disc areas.

The Phase I and Phase II clinical trials have separate and distinct primary and secondary endpoints. In Phase I (dose-escalation stage), the primary endpoints focus on safety while the secondary endpoints aim to identify a safe and potentially effective dose range and assess preliminary efficacy. All primary and secondary endpoints for the Phase I dose-escalation stage have been met in November 2025. All participants in Phase IIa have completed the last visit in the main study. The primary and secondary endpoints of Phase I clinical trials are set out in the table below. Additional endpoints and assessments were also evaluated but are not presented in the table below.

Phase I

Endpoint	Supporting Basis
Primary endpoints	
To assess, within 24 and 52 weeks after treatment, the types, severity, and incidence of ocular and non-ocular adverse events and serious adverse events, and to explore the maximum tolerated dose.	The safety profile was favorable. No participants experienced dose-limiting toxicity. No participants experienced serious adverse events related to the investigational product, and no participants experienced $\geq$ Grade 3 adverse events related to the investigational product.
Secondary endpoints	
To assess the mean change from baseline in best-corrected visual acuity (“BCVA”) at Week 52 post administration.	According to the interim report dated November 3, 2025, a subset of patients in Cohorts 1-4 had completed the Week 52 visit, and among these subjects, the mean BCVA improvements from baseline were 8.3, 5.3, 8.3, and 10.7 letters, respectively.

Clinical Trial in the United States

Overview. We have conducted separate Phase I and Phase II clinical trials of EXG102-031 (EXG102-031-211) in the United States to evaluate its safety, tolerability and preliminary efficacy in patients with wet age-related macular degeneration (wAMD).

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Trial Design. The study in the United States (EXG102-031-211) follows an open-label, multi-center, single-dose, 3+3 dose-escalation design. Patients in the U.S. study (EXG102-031-211) receive a single subretinal injection of EXG102-031 at ascending dose levels of 2.0×10^{10} , 4.0×10^{10} , 1.0×10^{11} and 1.8×10^{11} vg/eye.

For the key inclusion criteria and exclusion criteria of the study, please refer to the key inclusion criteria and exclusion criteria of the Phase I/II clinical trial in China.

All primary and secondary endpoints for the Phase I clinical trial have been met in February 2026, which have been set out in the table below. Additional endpoints and assessments were also evaluated but are not presented in the table below.

Phase I

Endpoint	Supporting Basis
Primary endpoints	
To assess, within 52 weeks after treatment, the incidence, types, and severity of ocular and non-ocular adverse events and serious adverse events.	The safety profile has been favorable, with no participants experiencing dose-limiting toxicity and no serious adverse events related to the investigational product.
Secondary endpoints	
To assess, within 24 weeks after treatment, the incidence, types, and severity of ocular and non-ocular adverse events and serious adverse events.	The safety profile has been favorable, with no participants experiencing dose-limiting toxicity and no serious adverse events related to the investigational product. All patients completed Week 52 visit and the mean BCVA improvements from baseline were 1.33, -3.67, 3.0, and 6.0 letters, respectively.
To assess the mean change from baseline in BCVA at Week 52 post administration.	

Trial Status and Data

Trial Status. EXG102-031 is currently being evaluated in two ongoing clinical trials: one in the United States and one in China.

In the United States, we obtained the approval from FDA and initiated the Phase I clinical trial in January 2023. The Phase I clinical trial was completed in March 2026.

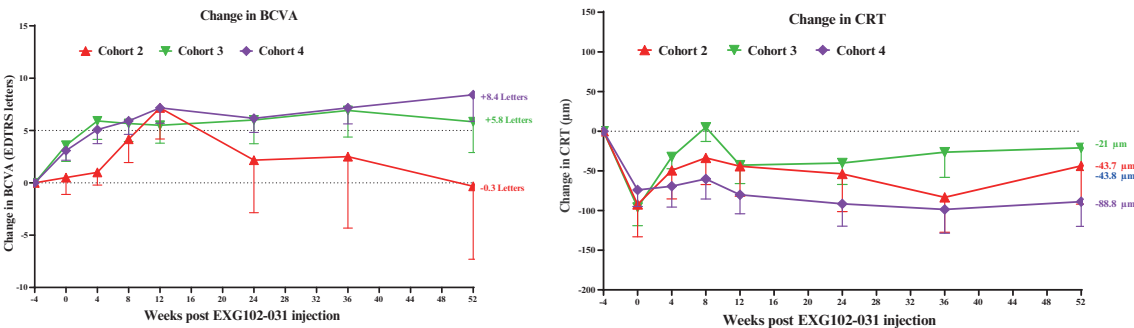
In China, we obtained the approval from NMPA for a combined Phase I/II clinical trial. The Phase I/II clinical trial was initiated in June 2023, in which the Phase I safety results were confirmed in August 2024, and the Phase II was initiated in September 2024. Currently, all patients in Phase I and IIa have completed the last visit (52-week) in the main study, and the Phase IIb/III trial is expected to commence in the second half of 2026.

Safety Data. EXG102-031 was generally well tolerated in the Phase I/II trial. No dose-limiting toxicities (DLTs) and no treatment-related serious adverse events (SAEs) were observed as of the Latest Practicable Date. Adverse events (AEs) were generally mild, transient, and manageable with standard clinical care.

Efficacy Data. Efficacy data demonstrated improvements in both visual acuity and anatomical outcomes, along with a substantial reduction in treatment burden. BCVA and CRT were consistently maintained or improved through 12 months of follow-up across cohorts (see BCVA and CRT graphs of Cohort 2-4 below). In the 1.8×10^{11} vg/eye dose (Cohort 4), ten out of twelve patients have not required any rescue treatment throughout the entire study year or during the long-term follow-up continued to date, and have shown progressive BCVA improvement through 52-weeks of follow-up. Beyond the BCVA and CRT improvements seen across all patients in Cohorts 2-4 (graphs below), the injectionfree subset also showed encouraging efficacy, with a mean BCVA gain of +8.6 ETDRS letters and a mean CRT reduction of 77.2 μ m.

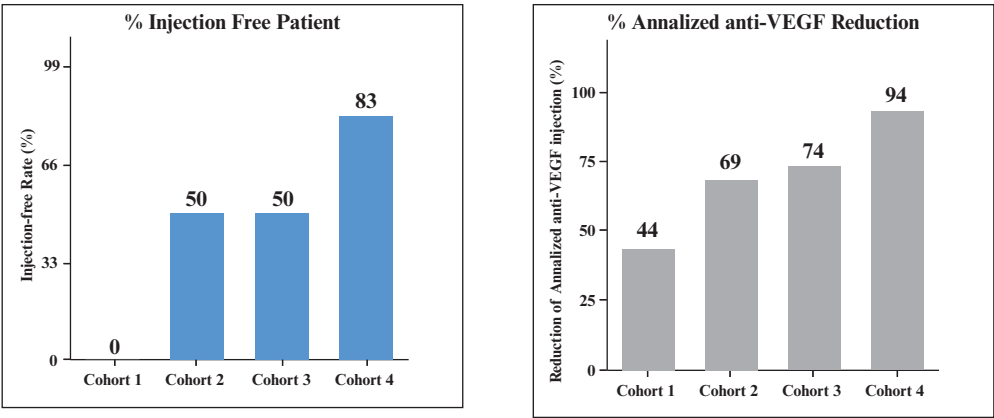
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Sustained and Dose-Dependent Improvement in Vision and Retinal Anatomy (Cohort 2-4)



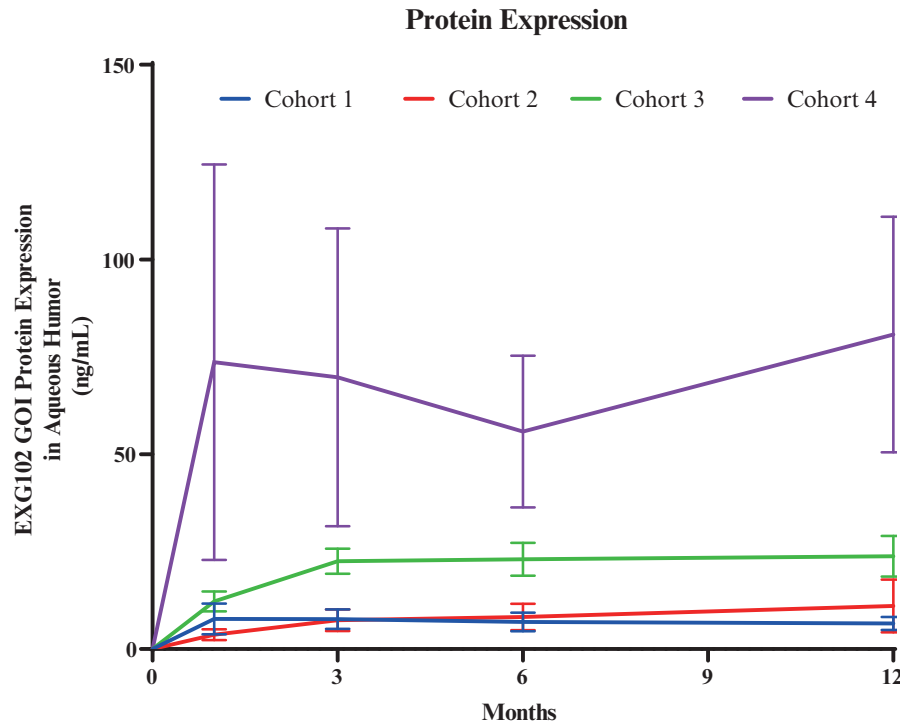
Patients demonstrated a dose-dependent reduction in supplemental anti-VEGF injection burden across all cohorts (see graphs below), which includes all the subjects in Cohort 2-4 at Week 52. At the 1.8×10^{11} vg/eye dose, approximately 83% of patients are projected to remain anti-VEGF injection-free through 12 months, and the annualized number of anti-VEGF rescue injections is reduced by up to 94.4%.

Dose-Dependent Reduction in Anti-VEGF Injection Burden



In addition, serial measurements of the multi-target protein encoded by EXG102-031 were performed in aqueous humor samples collected from patients over multiple timepoints following administration. The data demonstrated that the expression of this therapeutic protein was sustained throughout the observation period (up to 12 months) and exhibited a dose-dependent response profile.

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Note: Due to staggered enrollment, data availability varied across timepoints, as some patients had not yet reached later assessments.

Source: Company data

Clinical Development Plan

Long-term safety follow-up of up to five years is ongoing, in accordance with regulatory requirements for AAV-based gene therapy products. In China, all patients in Phase I and II have completed 52-week visit, the last visit in the main study, and the Phase IIb/III trial is expected to commence in the second half of 2026. In the United States, the Phase I clinical trial has been completed in the second half of 2026, and the FDA has no objection to the Company proceeding to the next phase of clinical trial. The next clinical trial in the U.S. will leverage insights from the rapidly progressing trials in China.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG102-031 SUCCESSFULLY.

EXG001-307 (SMA Type 1) — Our Core Product candidate

Overview

EXG001-307 (SMA Type 1) is an adeno-associated virus (AAV)-based gene therapy product candidate being developed as a differentiated treatment for spinal muscular atrophy type 1 (SMA Type 1), a rare and life-threatening neuromuscular disorder caused by a deficiency of survival motor neuron (SMN) protein. EXG001-307 (SMA Type 1) is designed as a gene replacement therapy to restore SMN expression in motor neurons while limiting the expression in non-neuronal tissues, with the goal of aiming to provide durable clinical benefit with improved safety through physiologically balanced expression across the central nervous system.

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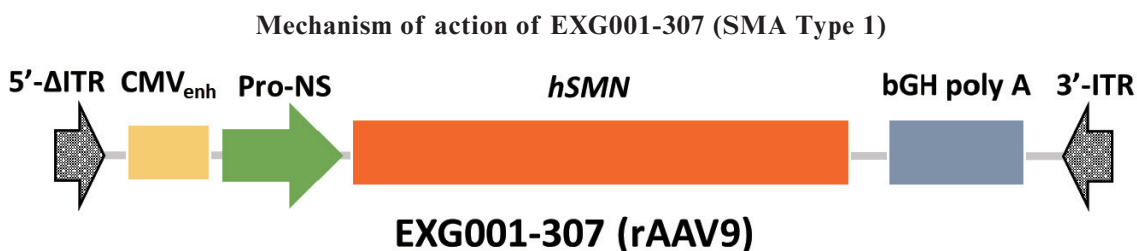
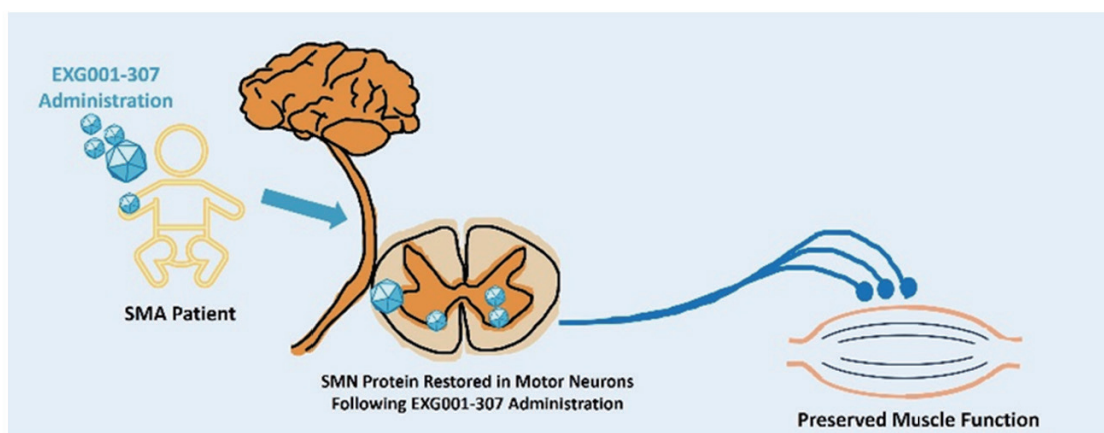
EXG001-307 (SMA Type 1) for the treatment of SMA Type 1 constitutes one of our Core Product candidates. EXG001-307 (SMA Type 1) received IND approval from the NMPA for the treatment of SMA Type 1 in June 2022. As of the Latest Practicable Date, we have completed the Phase I/II clinical trial of EXG001-307 (SMA Type 1) in China. As of the Latest Practicable Date, all surviving patients had completed the primary observation period through 18 months of age, and long-term four-year safety monitoring is ongoing.

Mechanism of Action

Spinal muscular atrophy (SMA) is caused by mutations in the SMN1 gene, resulting in a deficiency of the survival motor neuron (SMN) protein and progressive skeletal muscle atrophy that impairs movement, swallowing and respiration. SMA severity varies by age of onset, with infantile-onset SMA Type 1 presenting at or shortly after birth with severe weakness, respiratory involvement and early mortality.

EXG001-307 (SMA Type 1) employs a recombinant adeno-associated virus vector for gene replacement therapy, delivering a functional copy of the survival motor neuron (SMN) gene to restore deficient SMN expression. The vector incorporates a proprietary neuron-preferential promoter system combining a cytomegalovirus enhancer and the human synapsin (hSyn) promoter to drive selectively higher SMN expression in neuronal cells within the central nervous system while substantially limiting peripheral tissue expression.

Following a single intravenous administration, the AAV vector efficiently crosses the blood-brain barrier and delivers the functional SMN expression cassette primarily to motor neurons in the anterior horn of the spinal cord and brainstem, which are the key pathogenic cells in SMA patients.



Source: Company diagram

Taken together, EXG001-307 (SMA Type 1) is designed to restore SMN protein to near-physiological levels specifically within motor neurons, enabling functional recovery while minimizing off-target exposure. This neuronal expression-preferential strategy supports improved safety, durable SMN expression, and stronger efficacy relative to gene therapies using broad, ubiquitous promoters.

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Key Components

As a gene therapy drug candidate, the key components of EXG001-307, the function of each component, and ownership are shown in the table below:

Component	Function	Ownership
AAV9 wild type capsid	Vector used to deliver transgene to the target cells	The patent has expired and legally enters the public domain.
DNA construct expressing human SMN protein	To supplement the human SMN protein that the SMA patient lacks through gene expression.	The Company fully owns the patent of the construct design.

As advised by Zhonglun Law Firm, our intellectual property counsel, we confirm that we own the patents to the product EXG001-307 and the DNA construct listed above, while the full term of the patent on AAV9 wild type capsid has expired and such expired patent will not restrict our use of AAV9 wild type capsid in EXG001-307 or otherwise jeopardize the R&D and future commercialization of EXG001-307.

Given that the key differentiation of EXG001-307 from other comparable products currently on the market lies in the design of its payload, rather than the capsid, the expiration of AAV9 capsid patent protection and its entry into the public domain is not expected to adversely affect the market competitiveness of EXG001-307. Accordingly, even if we do not develop a novel capsid, we believe this would not impair the competitive position of EXG001-307.

Market Opportunity and Competition

Market Opportunity

Spinal muscular atrophy (SMA) is a rare, severe, and life-threatening neuromuscular disorder caused by insufficient levels of survival motor neuron (SMN) protein and is one of the most common fatal genetic diseases in infants and young children, with an estimated incidence of one in 6,000 to 10,000 live births. Among the clinical subtypes, SMA Type 1 is the most severe and prevalent form and is characterized by rapid motor neuron degeneration, profound muscle weakness, respiratory failure, and high early mortality without intervention.

The SMA therapeutic market has established a meaningful and growing commercial presence worldwide. In 2025, the global SMA drug therapy market reached US\$4.74 billion, and is projected to grow to US\$5.93 billion by 2030 and US\$9.45 billion by 2035. In China, the SMA drug therapy market was RMB587.9 million in 2025 and is expected to increase to RMB1,687.7 million by 2030 and RMB3,294.5 million by 2035. Commercial performance of approved therapies, including Zolgensma®, which generated approximately US\$2.4-2.6 billion in global sales between 2020 and 2025, underscores the scale and maturity of this market.

The SMA patient population also continues to expand as diagnostic coverage, genetic testing, and newborn screening improve worldwide. Globally, prevalence was approximately 176.9 thousand patients in 2025 and is projected to increase to 195.5 thousand by 2030 and 210.8 thousand by 2035. In China, prevalence reached 41.0 thousand in 2025 and is projected to reach 43.8 thousand by 2030 and 45.7 thousand by 2035. Together with persistently unmet clinical, economic, and functional needs, these trends highlight a substantial and growing market opportunity.

While disease-modifying treatments such as antisense oligonucleotides, small molecules, and gene replacement therapies have transformed the treatment landscape, significant unmet needs remain due to lifelong treatment requirements, declining adherence, high costs, and ongoing safety concerns.

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Leveraging our proprietary promoter design and AAV-based delivery system, EXG001-307 (SMA Type 1) is designed to achieve selective, physiologically balanced expression in motor neurons across the central nervous system, potentially offering an improved safety profile, enhanced durability, and greater accessibility for patients.

Current Treatment Options and Limitations

As of the Latest Practicable Date, available disease-modifying therapies (DMTs) for spinal muscular atrophy (SMA) include AAV-based gene therapy, antisense oligonucleotides (ASOs) and small-molecule splicing modifiers. Key marketed products are Zolgensma[®] (gene therapy for infants under 2 years old) and Itvisma[®] (intrathecal variant of Zolgensma[®] for 2 years of age and older patients), Spinraza[®] (ASO) and Evrysdi[®] (small molecule), all of which are approved in major global markets, with Spinraza[®] and Evrysdi[®] currently approved in China.

Zolgensma[®] and Itvisma[®] are the only approved SMA gene therapy products as of the Latest Practicable Date. While these products provide SMN gene replacement following a single administration, their use of a broad, ubiquitous CBA promoter drives transgene SMN expression across multiple organs, including non-critical peripheral tissues such as the liver and heart. This lack of expression control may increase systemic exposure and dose-related safety risks, including hepatic and cardiac toxicities and reported thrombotic microangiopathy events. In addition, Zolgensma[®]'s high upfront cost, exceeding US\$2 million per treatment in the United States, substantially limits patient access globally.

Spinraza[®] and Evrysdi[®] increase SMN protein levels through modulation of SMN2 splicing but require lifelong administration. Spinraza[®] requires repeated intrathecal injections via lumbar puncture, imposing ongoing procedural burden and contributing to declining adherence over time, while Evrysdi[®] depends on uninterrupted daily oral dosing to maintain efficacy. For both therapies, long-term treatment requirements, cumulative costs and adherence challenges continue to constrain real-world effectiveness and accessibility.

Overall, while current therapies have improved outcomes for some SMA patients, their limitations in efficacy, safety, mode and frequency of administration, long-term adherence and cost underscore the need for new gene therapies capable of durable and targeted restoration of physiologically balanced SMN expression in motor neurons across the CNS, together with an improved safety profile and better real-world accessibility.

Competitive Landscape

In the field of spinal muscular atrophy (SMA) gene therapy, the main international competitor is Zolgensma[®], an adeno-associated virus serotype 9 (AAV9)-based gene therapy developed by Novartis, together with its intrathecal formulation Itvisma[®]. Zolgensma has been approved in several major global markets, including the United States, the European Union, and Japan, and remains the only commercialized gene therapy for SMA worldwide. An intrathecally administered formulation version of Zolgensma[®], OAV101, was submitted for marketing approval in China in August 2025 and not yet approved as of the Latest Practicable Date.

Globally, several additional AAV-based SMA gene therapy candidates are under clinical development as of the Latest Practicable Date. These include ANB-004 (Biocad), currently in Phase I/II development for SMA, and GB221 (Gemma Biotherapeutics), also in Phase I/II development for SMA Type 1, as summarized in the following Table.

Global Competitive Landscape of SMA Drugs Pipeline

Pipeline	Company	Modality	Clinical Stage	Indication	First Posted Date
EXG001-307 . . .	ExeGenesis Bio	Gene Therapy	I/II	Spinal Muscular Atrophy (SMA) Type 1	2022/11/07
Apitegromab . . .	Scholar Rock	Antibody	BLA	Spinal Muscular Atrophy (SMA) Type 2/3	2025/2/8

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Pipeline	Company	Modality	Clinical Stage	Indication	First Posted Date
Salanersen	Biogen	Oligo	Phase III	Spinal Muscular Atrophy (SMA) Type 2	2025/10/28
NMD670	NMD Pharma	Small Molecule	Phase II	Spinal Muscular Atrophy (SMA) Type 3	2023/4/3
ANB-004	Biocad	Gene Therapy	Phase I/II	Spinal Muscular Atrophy (SMA)	2023/2/17
GB221	Gemma Biotherapeutics	Gene Therapy	Phase I/II	Spinal Muscular Atrophy (SMA) Type 1	2025/7/17

Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past three years.
5. Only include clinical trials that are above Phase I.

Source: Clinicaltrials.gov, Company website, Literature research, F&S Analysis.

In China, the SMA gene therapy landscape is expanding but remains at an early stage. As summarized in the Table below, the majority of these product candidates are in early-phase clinical or investigator-initiated trials. As of the Latest Practicable Date, no domestically developed gene therapy for SMA had received marketing approval in China or overseas, and Zolgensma® and Itivisma® remained the only commercialized AAV-based gene therapies worldwide.

China Competitive Landscape of SMA Drugs Pipeline

Pipeline	Company	Modality	Clinical Stage	Indication	First Posted Date
EXG001-307 . . .	Exegenes Bio	Gene Therapy	I/II	Spinal Muscular Atrophy (SMA) Type 1	2022/9/29
OAV101 IT	Novartis	Gene Therapy	BLA	Spinal Muscular Atrophy (SMA)	2025/8/2
GC101	GeneCradle	Gene Therapy	III	Spinal Muscular Atrophy (SMA) Type 2	2025/5/16
SKG0201	Lanyue Biotech	Gene Therapy	I/II	Spinal Muscular Atrophy (SMA) Type 1	2026/6/8

Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past three years.
5. Only include clinical trials that are above Phase I.

Source: CDE, Company website, Literature research, F&S Analysis

Competitive Advantage

EXG001-307 (SMA Type 1) is a differentiated gene therapy designed to address the key limitations of current SMA gene therapies related to safety, expression selectivity and accessibility, as exemplified by Zolgensma®. EXG001-307 (SMA Type 1) incorporates a neuron-preferential promoter to drive targeted expression of the SMN gene within the central nervous system while reducing expression in peripheral tissues such as the liver and heart, thereby reducing systemic exposure and supporting improved safety while maintaining physiologically balanced SMN restoration in motor neurons.

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Consistent with this targeted expression profile, EXG001-307 (SMA Type 1) exhibits a more favorable in vivo safety profile. EXG001-307 (SMA Type 1) exhibited markedly lower transgene expression in the heart and liver in mice, compared with a control construct using the broad, non-tissue-specific promoter configuration employed in Zolgensma[®], while maintaining equivalent expression in the spinal cord. In comparative toxicology studies, EXG001-307 (SMA Type 1) showed no apparent lethality at doses approximately three times higher than the lethal threshold observed with Zolgensma[®] — and no cardiomyocyte pathological abnormalities at the highest tested dose, representing a greater than 6-fold safety margin. In addition, EXG001-307 (SMA Type 1) demonstrated an approximately three-fold higher threshold for heart thrombosis and substantially reduced liver toxicity.

EXG001-307 (SMA Type 1) addresses the treatment-burden and adherence limitations of non-gene-replacement SMA therapies. Spinraza[®], the approved antisense oligonucleotide, requires long-term intrathecal administration by lumbar puncture, imposing a substantial and recurring procedural burden that contributes to declining adherence, while Evrysdi[®] depends on uninterrupted daily dosing, creating long-term adherence and treatment-burden challenges. By contrast, EXG001-307 (SMA Type 1) is designed as a single-dose intravenous therapy to provide durable SMN restoration in motor neurons, reducing the need for repeated procedures or lifelong administration and addressing limitations of current SMA treatments.

Clinically, as summarized in the table below, EXG001-307 (SMA Type 1) has demonstrated a favorable efficacy profile compared with the reported data of approved SMA therapies including Zolgensma[®], Spinraza[®], and Evrysdi[®]. As of the Latest Practicable Date, patients in the 1.5×10^{14} vg/kg cohort of our Phase I/II trial achieved a 100% of head-control ratio, numerically higher than the head-control ratio reported for Zolgensma[®] (approximately 78%-85%) and Evrysdi[®] (approximately 44%). Other milestone attainment was also notable: approximately two-thirds (66.7%) attained the ability to sit without support, two patients (22.2%) achieved standing with or without support, and one-third (33.3%) demonstrated stepping movements — levels of improvement that are substantially higher than those observed with existing SMA regimens.

Efficacy Comparison Across SMA Trials

	EXG001-307 (1.5×10^{14} vg/kg)	Zolgensma [®]	Zolgensma [®]	Evrysdi [®]	Nusinersen [®]
Trial (n of patients)	Phase 1/2 1.5×10^{14} vg/kg (n=9*)	STRIVE (n=22)	STRIVE-EU (n=33)	FIREFISH part2 (n=41)	ENDEAR (n=80)
Age at endpoint	18-month	18-month	18-month	12 months after treatment	394 days after treatment
CHOP-INTEND improvement	20.3	24	21	20	11
Head Control (≥3s)	100% (9/9) [#]	85% (17/20) ^{##}	78% (23/30) [#]	44% (18/41) [@]	—
Sitting without support (≥5s)	66.7% (6/9)	59% (13/22) [*]	49% (16/33)	29% (12/41)	8% (6/73) ^{@@@}
Standing with or without support (≥2s)	22.2% (2/9)	4.5% (1/22)	6% (2/33)	5% (2/41) ^{@@}	1% (1/73) ^{@@}
Stepping Movements	33.3% (3/9)	—	3% (1/33)	—	—

Note: These results were obtained from different trials and are not based on a head-to-head comparison.

* A total number of 10 patients were initially enrolled in this cohort. During the trial, one patient was excluded from the efficacy analysis due to death from pneumonia that occurred prior to efficacy assessment. The death was determined to be unrelated to the study drug and was instead attributed to extrinsic causes unrelated to the treatment.

#, ## Baseline head control; #: 3 subjects; ##: 2 subjects;

@, @@, @@@ HINE-2: @Able to maintain upright posture; @@HINE-2: Able to stand with support; @@@HINE-2: Able to sit stably and can pivot (rotate).

& sitting without support from this trial is >= 30s.

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Phase III Clinical Trial — SMA Type 1

Overview. We have completed a Phase I/II clinical trial of EXG001-307 (SMA Type 1) through intravenous administration in China to evaluate its safety, tolerability, and preliminary efficacy in patients with spinal muscular atrophy type 1 (SMA Type 1). The study consists of a Phase I dose-escalation stage followed by a Phase II dose-extension stage, both designed to assess safety and determine the recommended dose for subsequent clinical development.

Trial Design. The Phase I portion of the SMA Type 1 trial follows an open-label, multi-dose, dose-escalation design. Patients receive a single intravenous infusion of EXG001-307 (SMA Type 1) at ascending dose levels of 1.1×10^{14} vg/kg and 1.5×10^{14} vg/kg. Six subjects are enrolled in Phase I trial, with 28 days of safety observation between dose escalations. Dose escalation proceeds upon confirmation of safety and the absence of dose-limiting toxicities (DLTs) in the prior cohort.

Following the Phase I stage, the Phase II dose-extension cohort was initiated to further evaluate safety, tolerability, and efficacy at the recommended dose level. Seven subjects are enrolled in Phase II trial. Patients are continuously followed until 18 months of age (all were dosed before 6 months of age), with long-term safety follow-up extending to four years.

The key inclusion criteria for the study included but not limited to: (1) The patient has been diagnosed with SMA based on the presence of biallelic SMN1 mutations and has two copies of the SMN2 gene; (2) as of the dosing date, the patient is no older than 180 days after birth; and (3) the patient’s clinical history and signs are consistent with the manifestations of SMA Type 1.

The key exclusion criteria included but not limited to: (1) anti-AAV9 antibody titer > 1:50 (as measured by the ECL assay) or anti-AAV9 neutralizing antibody (NAb) titer > 1:100; (2) prior treatment with nusinersen injection, Zolgensma, or participation in any other clinical study for the treatment of SMA (except for patients who have completed a 7-day washout for risdiplam); and (3) Clinically significant abnormal laboratory values (GGT, ALT, and AST > $2.5 \times \text{ULN}$; total bilirubin $\geq 3 \times \text{ULN}$; creatinine $\geq \text{ULN}$; hemoglobin < LLN or ULN; white blood cell count > ULN or < LLN; neutrophils < LLN; lymphocytes < LLN; platelet count < LLN).

The Phase I and Phase II clinical trials have separate and distinct primary and secondary endpoints. In Phase I (dose-escalation stage), the primary endpoints focus on safety while the secondary endpoints aim to identify a safe and potentially effective dose range and assess preliminary efficacy. Since Phases I and II were conducted sequentially and both included a 1.5×10^{14} vg/kg dose cohort, efficacy analyses for this dose combined data from both phases, including only patients with ≥ 6 months of follow-up. All primary and secondary endpoints for the Phase I dose-escalation stage have been met in March 2025. The endpoints of Phase I clinical trials are set out in the table below. Additional endpoints were also evaluated but are not presented in the table below.

Phase I

Endpoint	Supporting Basis
Primary endpoints	
Adverse events, serious adverse events, and adverse events of special interest	All safety endpoints have been collected. No dose-limiting toxicity was observed. No AEs leading to dose reduction, dose interruption, or treatment discontinuation were reported.

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Endpoint	Supporting Basis
Secondary endpoints	
Proportion of subjects who, at the study visit upon reaching 18 months of age, achieve the ability to sit independently without support for ≥ 5 seconds	At 18 months of age, no subjects in the 1.1×10^{14} vg/kg dose group achieved independent sitting without support for ≥ 5 seconds; among the nine subjects from the 1.5×10^{14} vg/kg dose cohort from both Phase I and II, six (66.7%) achieved sitting without support for ≥ 5 seconds.
Event-free survival rate at 18 months of age	At 18 months of age, the event-free survival rate was 100.0% among all the six (6) subjects in the 1.1×10^{14} vg/kg and 1.5×10^{14} vg/kg dose groups.
Proportion of subjects with a CHOP-INTEND score of ≥ 40 at the study visit upon reaching 18 months of age	At 18 months of age, all the three (3) subjects in the 1.1×10^{14} vg/kg dose group had a CHOP-INTEND score of ≥ 40 . Data from the 1.5×10^{14} vg/kg dose cohort in Phase I have been incorporated in the Phase II dataset.

In Phase II (dose-expansion stage), the primary endpoints focus on efficacy while the secondary endpoints aim to assess efficacy and safety. All primary and secondary endpoints for the Phase II dose- expansion stage have been met in August 2025. The endpoints of Phase II clinical trials are set out in the table below. Since Phases I and II were conducted sequentially and both included a 1.5×10^{14} vg/kg dose cohort, efficacy analyses for this dose combined data from both phases, including only patients with ≥ 6 months of follow-up. Additional endpoints and assessments were also evaluated but are not presented in the table below.

Phase II

Endpoint	Supporting Basis
Primary endpoints	
At the study visit upon reaching 18 months of age, the proportion of subjects who achieved independent sitting without support for ≥ 5 seconds.	At 18 months of age, among the nine subjects in the efficacy analysis set from the 1.5×10^{14} vg/kg dose cohort, six (66.7%) achieved sitting without support, which was significantly higher ($P < 0.0001$) than the natural history rate (0%).
Secondary endpoints	
At the study visit upon reaching 18 months of age, the proportion of subjects with a CHOP-INTEND score of 40 or above.	At 18 months of age, eight out of nine subjects (88.9%) in the 1.5×10^{14} vg/kg dose cohort had a CHOP-INTEND score of ≥ 40 , which was significantly higher (all P values < 0.0001) than the natural history rate (0%).

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Endpoint	Supporting Basis
At the study visit upon reaching 18 months of age, the proportion of subjects who achieved independent sitting for ≥30 seconds without support and standing.	At 18 months of age, three out of nine subjects (33.3%) in the 1.5×10^{14} vg/kg dose cohort achieved independent sitting for ≥30 seconds without support, and two subjects (22.2%) achieved assisted standing. The proportions of subjects achieving independent sitting for ≥30 seconds without support and assisted standing were significantly higher ($P < 0.0001$) than the natural history rate (0%).
Types and incidence of AEs, SAEs, and AESIs.	No adverse events leading to dose reduction, dose interruption, or treatment discontinuation were reported. The most common treatment-emergent adverse events related to EXG001-307 were increased aspartate aminotransferase (100.0%), pyrexia (92.3%), and decreased platelet count (76.9%), which were predominantly Grade 1–2 in severity. Drug-related serious adverse events included decreased platelet count, thrombotic microangiopathy, and myocardial injury.

SMA Type 1 Phase III Trial Status and Data

Trial Status. In June 2022, we obtained the approval from the China NMPA and commenced our Phase I/II combined clinical trials. We completed the Phase I clinical trial in April 2024. Following approval by the Data and Safety Monitoring Board in April 2024, we advanced into the Phase II clinical trial. We completed phase I & II clinical trial in November 2025. Formal discussions with the China NMPA will be initiated regarding the Phase III trial design in 2026 H2.

Safety Data. EXG001-307 was generally tolerated in the SMA Type 1 Phase I/II trial. Among the 13 subjects, nine subjects (69.2%) experienced SAEs, including three (23.1%) with SAEs considered related to EXG001-307. Among them, two subjects developed thrombotic microangiopathy (TMA). In both cases, the TMAs had either largely or completely resolved by the end of the study. No subject experienced an EXG001-307-related death. None of such adverse events led to patient withdrawal or study discontinuation. All AESIs and SAEs have been reported to the Ethics Committee, DSMB and regulatory authorities in accordance with applicable regulations.

Efficacy Data. Efficacy data demonstrated encouraging clinical outcomes, supporting meaningful developmental milestones in patients receiving the 1.1×10^{14} vg/kg and 1.5×10^{14} vg/kg dose EXG001-307 (SMA Type 1) (see table below). Outcomes in the 1.5×10^{14} vg/kg cohort were particularly notable. All patients (9/9), who were able to attend the efficacy evaluations, achieved head control, approximately two-thirds (6/9) attained the ability to sit without support, two patients (2/9) were able to stand with support, and three patients (3/9) were able to make stepping movements at the 18 months of age study visit.

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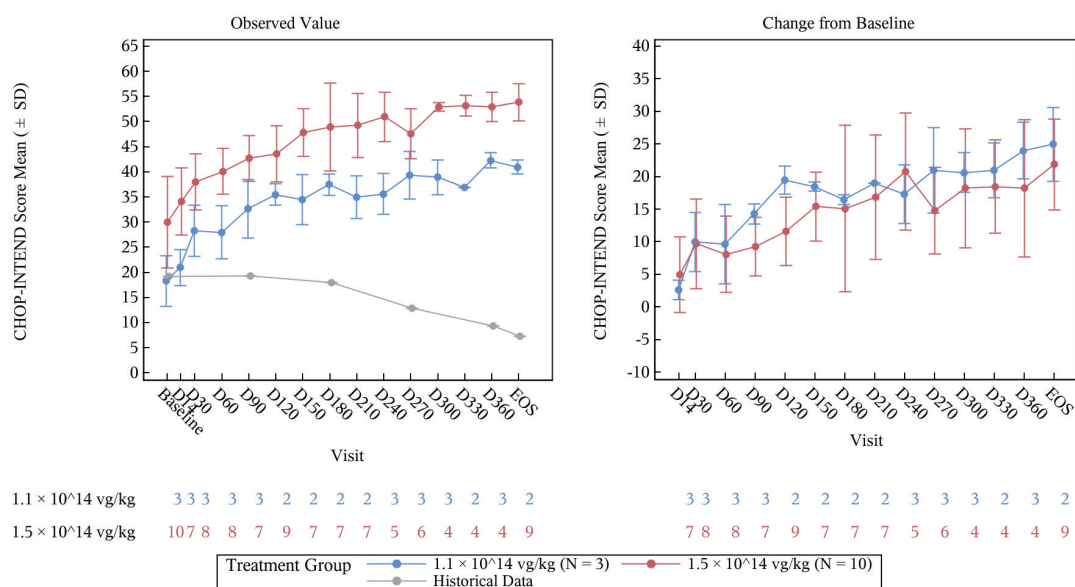
	1.1×10^{14} vg/kg n (%) [#]	1.5×10^{14} vg/kg n (%) ^{*,#}
18 months of age.	3 (100%)	9 (100%)
Head control ≥ 15 s.	3 (100%)	9 (100%)
Sits without support: ≥ 5 s.	0	6 (66.7%)
Sits without support: ≥ 30 s.	0	3 (33.3%)
Stands with assistance (Supports weight ≥ 2 s).	0	2 (22.2%)
Makes stepping movements.	0	3 (33.3%)
CHOP-INTEND ≥ 40	3 (100%)	8 (88.9%)

Note: * A total number of 10 patients were initially enrolled in this cohort. During the course of the trial, one patient was excluded from the efficacy analysis due to death from pneumonia occurring prior to efficacy assessment, following the family's decision to withdraw supportive care.

[#]Three patients (1 in 1.1×10^{14} vg/kg dose cohort, 2 in 1.5×10^{14} vg/kg dose cohort) received Risdiplam before 18-months of age. However, all motor milestones reported in the table were achieved before Risdiplam exposure.

In addition, 91.7% patients (11/12) in efficacy analysis set in both the 1.5×10^{14} vg/kg and 1.1×10^{14} vg/kg dose cohorts who reached the 18-months of age for motor evaluation achieved a CHOP-INTEND score of ≥ 40 by the end of study (EOS), reflecting meaningful improvements in motor function (Mean CHOP-INTEND score change from baseline refer to the figure below).

Mean CHOP-INTEND score change from baseline



Source: Company clinical study report.

As illustrated in the figure above, EXG001-307 (SMA Type 1) treatment was associated with an increased mean CHOP-INTEND trajectory over time. By contrast, patients in the natural history cohorts exhibited persistently low baseline CHOP-INTEND scores beyond six months of age and did not achieve the milestone of independent sitting. Taken together, these results suggest sustained functional benefit and are consistent with a dose-response relationship observed across cohorts.

Clinical Development Plan

The clinical protocol for EXG001-307 (SMA Type 1) dated February 20, 2022 and the NMPA approval dated June 21, 2022 clearly specify that the clinical trial for EXG001-307

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(SMA Type 1) is a combined Phase I/II study. The Phase I clinical trial adopts a dose-escalation design to assess the safety of ascending dose levels. Based on the Phase I safety and efficacy data, a recommended dose will be selected for expansion in the Phase II clinical trial.

According to the clinical protocol, progression from dose escalation (Phase I) to dose expansion (Phase II) does not require additional regulatory approval from the NMPA. Instead, advancement to Phase II clinical trial only requires review by an independent Data and Safety Monitoring Board (DSMB), which is responsible for the ongoing assessment of participants’ safety data.

The Phase I trial enrollment of this study was completed on November 18, 2023. On December 15, 2023, the DSMB committee approved progression to the Phase II expansion phase at the 1.5×10^{14} vg/kg dose. Post DSMB approval, we commenced the phase II trial and the first patient in phase II was dosed on February 28, 2024.

As of the Latest Practicable Date, all participants enrolled in the Phase II clinical trial had completed the end-of-study follow-up, marking the completion of the Phase I/II clinical trials. The clinical database has been locked, and the Clinical Study Report was completed in May 2026. We plan to initiate the discussion with the NMPA regarding the Phase III trial design in 2026 H2. The Phase III trial will be funded by internal resources.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG001-307 SUCCESSFULLY.

EXG202 - Key Product Candidate

Overview

EXG202 is a one-time, IVT-administered AAV-based gene therapy product candidate for the treatment of fundus neovascularization diseases (FNDs), including wet age-related macular degeneration (wAMD), a severe form of age-related macular degeneration characterized by fundus neovascularization, diabetic macular edema (DME) and retinal vein occlusion (RVO).

While our initial focus is on wAMD, we are strategically expanding our Key Product pipeline to target other fundus neovascularization diseases, specifically diabetic macular edema (DME) and retinal vein occlusion (RVO). While all three diseases are driven by VEGF-induced vascular leakage, the pathology in DME and RVO is intraretinal, making the tissue more fragile and the target site more accessible from the vitreous than in wAMD. To enable safe and efficacious treatment of DME and RVO, we are developing a novel AAV capsid designed for efficient retinal transduction via intravitreal (IVT) injection. This strategy aims to deliver a single-dose gene therapy for DME and RVO with an optimized efficacy and safety profile.

EXG202 utilizes our proprietary EOC024 capsid engineered using our AI-aided *AAVarta* platform. The EOC024 capsid is specifically designed to efficiently traverse the inner limiting membrane (ILM) following IVT administration. This property enables broad and efficient transduction across retinal cell types, positioning EXG202 as a differentiated intravitreal gene therapy for wAMD, DME, and RVO.

The capsid-optimized IVT delivery route provides significant clinical and strategic advantages. As a minimally invasive, non-surgical outpatient following IVT administration procedure, it is highly scalable for routine clinical practice, enabling access to a broad patient population. IVT delivery supports uniform retinal exposure, thereby maximizing the therapeutic potential of our engineered capsid.

With respect to the therapeutic payload, EXG202 encodes a proprietary multi-target anti-angiogenic fusion protein. Once transduced and expressed in retinal pigment epithelium (RPE) cells and photoreceptor cells, this fusion protein inhibits all the key angiogenic pathways including VEGF-A/B, VEGF-C/D, placental growth factor (PlGF), and Angiopoietin-2 (Ang2), thereby reducing fundus neovascular growth, vascular leakage and retinal edema.

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EXG202 received IND approval from the FDA in July 2025 and from the NMPA in August 2025. An investigator-initiated trial (IIT) commenced in May 2025, followed by the initiation of IND Phase I/II clinical trials in November 2025.

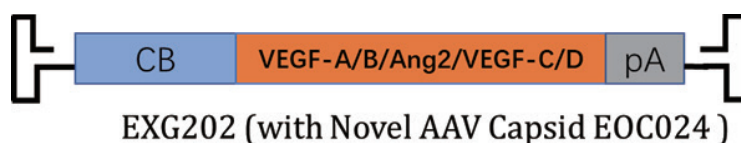
Mechanism of Action

Fundus neovascularization disease (FND) is driven by dysregulated angiogenesis involving multiple VEGF and angiopoietin-2 pathways. VEGF-A, VEGF-B, VEGF-C, VEGF-D and PlGF promote abnormal fundus neovascular proliferation and vascular leakage through activation of VEGFR1, VEGFR2 and VEGFR3, while Ang2 destabilizes retinal vasculature and potentiates VEGF-driven leakage and inflammation. Current standard anti-VEGF therapies primarily inhibit VEGF-A — or, in dual-target agents such as faricimab, VEGF-A and Ang2 — resulting in incomplete suppression of angiogenic signaling and compensatory upregulation of VEGF-C, VEGF-D and Ang2, which contributes to recurrent disease activity and limited durability.

EXG202 is administered via intravitreal (IVT) injection. Following delivery and transduction of retinal cells, transduced RPE cells and photoreceptor cells express a proprietary multi-target fusion protein, which simultaneously inhibits VEGF-A/B, VEGF-C/D, PlGF, and Ang2. This coordinated multi-pathway suppression blocks VEGFR1/2/3-mediated neovascular proliferation, reduces vascular leakage and stabilize endothelial integrity through inhibition of the Ang2-Tie2 signaling axis. By targeting all the key angiogenic pathways implicated in FND, EXG202 aims to overcome compensatory escape pathways, enhance durability of disease control and reduce the likelihood of recurrent exudation.

Compared with alternative delivery routes such as suprachoroidal (SCS) or subretinal administration, intravitreal (IVT) administration is a non-surgical, outpatient procedure that is more readily scalable in routine clinical practice and enables treatment of a broader patient population. IVT delivery provides uniform retinal exposure, supporting consistent intraocular transgene distribution.

EXG202: AAV construct design



The intravitreal delivery of EXG202 and transduction of retinal cells are further enabled by a proprietary AI-engineered AAV capsid EOC024. This novel AAV capsid EOC024 is specifically engineered to traverse the inner limiting membrane, a major barrier to intravitreal gene delivery, and to transduce retinal cells — including RPE and photoreceptor cells — more efficiently and uniformly than conventional AAV2 and AAV8 capsids or AAV2-derived variants such as AAV2.7m8. In nonhuman primate studies, EXG202 demonstrated approximately 2- to 5-fold higher levels of therapeutic protein expression in retinal tissues compared with benchmark intravitreal AAV capsids, including those used in current investigational gene therapies. This enhanced retinal penetration enables widespread, durable expression of the multi-target fusion protein from a single IVT injection, a long-lasting expression profile that is intended to reduce reliance on frequent intravitreal injections, address real-world adherence limitations and provide sustained suppression of pathological angiogenesis.

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Market Opportunity and Competition

Market Opportunity

FND, mainly including wAMD, DME, and RVO, represent a large and growing group of vision-threatening disorders and are among the leading causes of irreversible vision loss globally. According to Frost & Sullivan, in 2025, the global prevalence of FND reached approximately 85.1 million patients, and is projected to increase to 91.9 million by 2030 and 99.0 million by 2035, driven by population aging, rising diabetes prevalence and improved disease detection. In China, the FND population reached 20.2 million in 2025 and is expected to grow to 21.8 million by 2030 and 23.1 million by 2035.

Reflecting this expanding patient population and the chronic nature of these conditions, the global FND drug therapy market reached approximately US\$17.9 billion in 2025 and is expected to grow to US\$30.7 billion by 2030 and US\$55.8 billion by 2035, according to Frost & Sullivan, representing accelerating growth over time. In China, the FND drug therapy market reached approximately RMB6.0 billion in 2025 and is projected to expand to RMB17.5 billion by 2030 and RMB45.2 billion by 2035, supported by rapid patient growth, improving access to retinal care and increasing adoption of advanced therapies.

As such, there is a growing unmet clinical and commercial need for durable, effective and accessible therapies capable of providing sustained disease control, creating a significant opportunity for AAV-based gene therapies within the FND market.

Current Treatment Options and Limitations

As of the Latest Practicable Date, treatment for FND, primarily relies on anti-VEGF intravitreal injections. These include Ranibizumab (Lucentis[®]), Aflibercept (Eylea[®]), Faricimab (Vabysmo[®]), and are often supplemented by laser therapy, photodynamic therapy, or surgical interventions in advanced cases.

The current anti-VEGF therapies face significant biological limitations. While some approved agents inhibit more than one ligand (e.g., Eylea[®] and Lumitin[®] bind VEGF A/B and PlGF, and Vabysmo[®] targets Ang2 in addition to VEGF-A), none provide comprehensive suppression of all the key angiogenic drivers implicated in FND. Incomplete inhibition of pathways involving VEGF-C/D and Ang2 may allow compensatory signaling, contributing to persistent or recurrent disease activity and limited durability of response. Consequently, all approved anti-VEGF therapies require frequent and long-term intravitreal injections to maintain disease control, which imposes substantial treatment burden, contributes to poor real-world adherence, and is associated with cumulative procedural risks such as intraocular inflammation or infection. Together with variable efficacy, and limited durability, these limitations underscore a clear unmet need for sustained therapies for FND.

Competitive Landscape

Anti-VEGF monoclonal antibodies and fusion proteins remain the standard of care for FND and represent the primary competitors to EXG202 today. Approved products include Lucentis[®] (ranibizumab); Eylea[®] (aflibercept), Lumitin[®] (conbercept), and Vabysmo[®] (faricimab-svoa). These therapies are approved in major global markets as of the Latest Practicable Date.

In parallel, several AAV-based gene therapies for FND are in clinical development. The most advanced include ABBV-RGX-314 (Regenxbio), an AAV8-based gene therapy delivered via subretinal injection and currently in Phase III development, and ADV-022 (Adverum Biotechnologies), an intravitreally administered AAV-based gene therapy in Phase III trials. A third global clinical-stage program, 4D-150 (4D Molecular Therapeutics), is an intravitreally delivered AAV-based gene therapy targeting VEGF-A, VEGF-B, VEGF-C and PlGF and has also progressed to Phase III development. As of the Latest Practicable Date, no gene therapy for FND has been approved in the United States, Europe, Japan or any other major market.

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Global Competitive Landscape of Gene Therapy Pipelines for Treatment of wAMD/DME/RVO

Drug Name/Code	Target	Company	Clinical Stage	Indication	First Posted Date
EXG202	VEGF-A/B/C/D, Ang2, PlGF	ExeGenesis Bio	Phase I/II	nAMD	2025/9/17
EXG102-031	VEGF-A/B/C/D, Ang2, PlGF	ExeGenesis Bio	Phase I/II	wAMD	2023/6/6
ABBV-RGX-314	VEGF	AbbVie	Phase II/III Phase II	nAMD DME	2021/1/12 2025/4/16
Ixoberogene Soroparvovec.	VEGF	Adverum Biotechnologies	Phase III	nAMD	2025/3/4
4D-150.	VEGF-A/B/C, PlGF	4D Molecular Therapeutics	Phase III Phase II	nAMD DME	2025/3/7 2023/7/5
NG101.	VEGF-A	Neuracle Genetic	Phase I/II	nAMD	2023/8/9
KH631.	VEGF	Kanghong Pharmaceutical	Phase I	nAMD	2022/12/10
KH658.	VEGF	Kanghong Pharmaceutical	Phase I	nAMD	2025/2/8

Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past five years.

Source: Clinicaltrials.gov, Company website, Literature research, F&S Analysis

In China, the FND gene therapy landscape is expanding but remains in early stages of development. Both international and domestic companies are advancing AAV-based programs, including LX102 (Innostellar Biotherapeutics), RRG001 (RRGene Therapeutics), SKG0106 (Skyline Therapeutics), XMVA09 (Starry Gene), AL-001 (Anlong Bio), JWK001 (Genevector), IVB103 (InnoVec Bio), FT-003 (Frontera Therapeutics), KH631 and KH658 (Kanghong Pharmaceutical). With the exception of more advanced global candidates such as RGX-314, ADVN-022 and 4D-150, the majority of these programs remain in early-phase clinical or investigator-initiated trials.

China Competitive Landscape of Gene Therapy Pipelines for Treatment of wAMD/DME/RVO

Drug Name/Code	Target	Company	Clinical Stage	Indication	First Posted Date
EXG102-031 . .	VEGF-A/B/C/D, Ang2	ExeGenesis Bio	Phase I/II	wAMD	2023/10/12
EXG202	VEGF-A/B/C/D, Ang2	ExeGenesis Bio	Phase I/II	wAMD	2025/9/18
AL-001	VEGF	Anlong Bio	Phase II	wAMD	2025/2/18
HX9428	VEGFR2	Fujian Haixi Pharmaceuticals	Phase II	wAMD	2026/07/30
LX102	VEGF	Innostellar Biotherapeutics	Phase III	nAMD	2026/01/24
KH631	VEGF	Kanghong Pharmaceutical	Phase I/II	nAMD	2023/2/2
FT-003	VEGF	Frontera Therapeutics	Phase I/II	nAMD	2023/8/21

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Drug Name/Code	Target	Company	Clinical Stage	Indication	First Posted Date
FT-003	VEGF	Frontera Therapeutics	Phase I/II	DME	2023/10/27
RRG001	VEGF	RRGENER Therapeutics	Phase I/II	nAMD	2023/11/21
SKG0106	VEGF-A	Skyline Therapeutics	Phase I/II	nAMD	2023/12/27
XMVA09	ANGPT2, VEGF-A	Starry Gene	Phase I/II	wAMD	2024/4/12
JWK001	VEGF	Genevector	Phase I/II	nAMD	2024/5/30
KH658	VEGF	Kanghong Pharmaceutical	Phase II	nAMD	2026/7/7
IVB103	NA	InnoVec Bio	Phase I/II	nAMD	2024/11/29
NGGT007	NA	Next Generation Gene Therapeutics	Phase I/II	nAMD	2025/1/16
CRG-B191	VEGF	CorreGe	Phase I/II	wAMD	2025/11/6
YP004	VEGF	Yuanpu Biotechnology	Phase I	Neovascular (wet) age-related macular degeneration (nAMD)	2026/7/17
QBR202	–	Quaerite Biopharm	Phase I	Diabetic macular edema (DME)	2026/2/12
GB10	VEGF/Ang-2	Kexing	Phase I	Neovascular (wet) age-related macular degeneration (nAMD)	2026/1/26

Notes:

1. The industry information is as of 2026/08/23.
2. First posted date refers to the date on which the study record was first available on Chinadrugtrials.org.cn or Clinicaltrials.gov.
3. The clinical stage refers to the latest clinical trials as well as the first posted date.
4. Only includes pipelines active within the past three years.

Source: CDE, Company website, Literature research, F&S Analysis

As of the Latest Practicable Date, no AAV-based FND gene therapy has been approved in China or overseas, and all candidates remain under clinical investigation.

Competitive Advantage

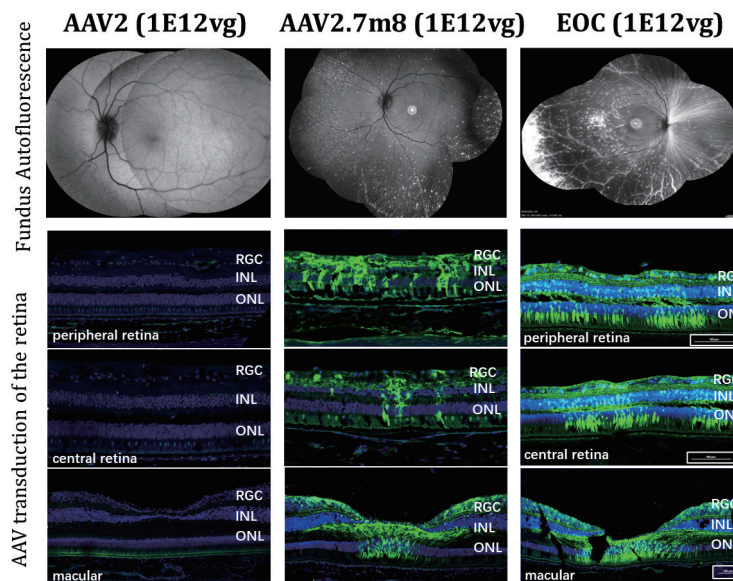
EXG202 addresses the incomplete inhibition limitation by expressing a proprietary multi-target anti-angiogenic fusion protein comprising the ligand-binding domains of VEGFR1, VEGFR2 and VEGFR3 together with an Ang2-binding domain. This design enables coordinated inhibition of all key angiogenic pathways including VEGF-A/B, VEGF-C/D, PlGF, and Ang2. By simultaneously blocking these angiogenic drivers, EXG202 is intended to suppress compensatory upregulation of VEGF-C/D and Ang2, which frequently occurs under VEGF-A-selective therapy, thereby supporting more durable and consistent suppression of fundus neovascular growth, vascular leakage and retinal edema. This multi-pathway design directly targets known mechanisms underlying incomplete response and disease recurrence observed with anti-VEGF monotherapy and with single-pathway gene therapies under development.

Further, EXG202 incorporates a proprietary AAV capsid that is engineered through our AI-aided *AAVarta* platform specifically for intravitreal delivery to improve retinal transduction efficiency. Conventional wild-type capsids such as AAV2 or AAV8, as well as wild-type-derived variants used in other intravitreal gene therapy programs, penetrate the inner limiting membrane (ILM) inefficiently and achieve limited transduction of deeper retinal layers. By contrast, EXG202’s EOC024 capsid is engineered to enhance inner limiting membrane traversal, broaden lateral and vertical retinal coverage and significantly improve transduction efficiency across RPE cells, photoreceptor cells and other clinically relevant retinal layers. In nonhuman primate studies, EXG202’s EOC024 capsid demonstrated superior GFP expression (see figure below) and approximately 2- to 5-fold higher levels of therapeutic

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protein expression in retinal tissues than the benchmark AAV2.7m8, an intravitreally administered AAV2 variant known for its inner limiting membrane penetration capability. This enhanced delivery profile is intended to enable more consistent and widespread intraocular expression of the therapeutic fusion protein, thereby supporting greater durability and superior therapeutic potential compared with first-generation intravitreal AAV vectors.

Enhanced Retinal Transduction with EOC024 Capsid Following Intravitreal Delivery Compared with AAV2.7m8



Source: Company data

Taken together, EXG202’s novel multi-pathway payload design and AI-engineered capsid, combined with intravitreal delivery, are intended to address the key limitations of currently available anti-VEGF therapies and investigational gene therapy candidates for FND, including insufficient pathway coverage, limited durability, delivery constraints and substantial real-world treatment burden.

Investigator Initiated Trial and IND Trial

Overview. We are conducting an investigator-initiated trial (IIT) and an IND Phase 1/2 trial of EXG202 to further evaluate its safety, tolerability and preliminary biological activity following intravitreal administration in patients with wAMD. This IIT is designed to complement our IND clinical program by providing early insights into the safety profile and potential therapeutic effects of EXG202.

Trial Design. The IIT is a single-center, open-label study evaluating three planned dose cohorts, with a total target enrollment of up to 15 subjects. EXG202 is administered as a single intravitreal injection, and patients are monitored for safety, tolerability and early signals of biological activity, including the improvement of visual acuity and anatomical outcomes, along with the need for standard anti-VEGF rescue therapy.

The key inclusion criteria for the study included but not limited to: (1) age ≥ 50 years; (2) a confirmed diagnosis of wAMD and currently receiving anti-VEGF treatment and/or having active lesions; (3) a BCVA score between 14 and 73 letters; and (4) a clinically meaningful prior response of the study eye to anti-VEGF therapy.

The key exclusion criteria included but not limited to: (1) the presence in the study eye of any ocular disease other than wAMD that may affect central vision or macular assessments; (2) a history of retinal detachment in the study eye or evidence of retinal detachment during screening; (3) MNV due to causes other than wAMD in the study eye, or a history of macular pathology unrelated to wAMD; (4) subretinal hemorrhage involving the fovea in the study eye with a hemorrhage area ≥ 4 disc areas; and (5) current vitreous hemorrhage of $\geq 1+$ in the study eye.

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Trial Status. As of the Latest Practicable Date, a total of seven patients were dosed across three cohorts at the following levels: 3×10^{10} vg/eye (n=4), 6×10^{10} vg/eye (n=2), and 1×10^{11} vg/eye (n=1). The first enrolled patient has completed one year of follow-up. In addition to the IIT trial, 17 patients have already been enrolled into IND Phase 1/2 trial, across four dose levels: 3×10^{10} vg/eye (n=3), 6×10^{10} vg/eye (n=5), 1×10^{11} vg/eye (n=6), and 1.8×10^{11} vg/eye (n=3).

Safety Data. EXG202 has been generally well tolerated in both IIT and IND trials to date.

Efficacy Data. Preliminary signs of therapeutic activity have been observed. Sustained stabilization of central retinal thickness (CRT) and maintenance of baseline best-corrected visual acuity (BCVA) have been consistently observed. Furthermore, the requirement for anti-VEGF rescue therapy has demonstrated a marked reduction, with the overall rescue injection rate falling significantly compared to the pre-study baseline. These findings suggest durable anatomic and functional control by intravitreal injection of EXG202. Additional safety and efficacy data continue to be collected as follow-up progresses.

Clinical Development Plan

EXG202 is currently being evaluated in two ongoing clinical trials: one in the United States and one in China.

In the United States, we obtained the IND approval from FDA in July 2025. However, we are not currently conducting clinical trials in the United States. We plan to bypass the U.S.-based Phase I study and directly proceed to a Phase II trial by leveraging Phase I data generated in China.

In China, we obtained the approval from NMPA in August 2025 to initiate a combined Phase I/II clinical study. The Phase IIa clinical trial was initiated in March 2026 and the Phase IIb clinical trial is expected to occur in the second half of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG202 SUCCESSFULLY.

EXG110

EXG110 is an adeno-associated virus (AAV)-based gene therapy product candidate under development for the treatment of Fabry disease, an X-linked lysosomal storage disorder caused by deficiency of α -galactosidase A (GLA). EXG110 is designed to enable durable, systemic restoration of GLA activity following a single intravenous administration, with the goal of reducing long-term treatment burden and providing sustained disease control.

Fabry disease represents a well-established therapeutic market with significant unmet medical need. According to Frost & Sullivan, global Fabry disease prevalence reached approximately 632.4 thousand patients in 2025 and is projected to increase to 723.3 thousand by 2030 and 819.6 thousand by 2035. Approved therapies include enzyme replacement therapies and an oral chaperone therapy. In 2025, Fabrazyme[®] generated global sales of €1.019 billion (approximately US\$1.15 billion) while Galafold[®] generated global sales of US\$521.7 million. However, current treatments require lifelong frequent administration, provide intermittent enzyme exposure, and may not fully prevent disease progression, particularly in critical organs such as heart and kidney, due to limited penetration of the current enzyme replacement treatment into these key diseased tissues. In addition, chaperone therapy is limited to patients with amenable GLA mutations.

EXG110 is designed to address these limitations by enabling sustained endogenous production of GLA following a single administration. EXG110 incorporates a proprietary muscle-tropic AAV capsid, developed through the Company's AI-aided *AAVarta* platform, together with a liver- and muscle-bispecific promoter. This design supports efficient systemic delivery and drives trans-GLA expression in both hepatic and extrahepatic tissues, including skeletal muscle and cardiomyocytes.

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Hepatic expression enables early secretion of circulating GLA, while sustained expression in largely non-dividing tissues such as muscle is intended to provide long-term intracellular enzyme production. This dual-tissue expression strategy therefore enhances enzyme delivery to organs that are inadequately addressed by existing therapies, particularly the heart, and to support more durable GLA activity than liver-directed approaches alone.

Preclinical studies in Fabry mouse models demonstrated durable GLA activity, broad tissue distribution and effective substrate clearance following a single intravenous administration. In nonhuman primates, EXG110, administered at a 3-fold lower dose, achieved rapid and sustained circulating enzyme activity at levels approximately 85-fold higher than the benchmark liver-directed AAV therapy ST-920 (Sangamo Therapeutics). These findings suggest that our novel capsid enables more efficient transduction and broader extra-hepatic expression in tissues such as muscles and cardiomyocytes, indicating its potential for better clinical outcomes.

EXG110 is currently being evaluated in IND Phase I clinical and investigator-initiated trials. Early clinical data have demonstrated a favorable initial safety profile, and further evaluation of safety and efficacy is ongoing. Completion of the Phase I study is currently targeted for the second half of 2028, after which the program is expected to advance into Phase II/III clinical development, subject to regulatory review and clinical outcomes.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG110 SUCCESSFULLY.

EXG112

EXG112 is a non-opioid pain therapy program targeting Nav1.7 (SCN9A), a key regulator of pain signaling of peripheral sensory neurons. The program is primarily focused on a synthetic antisense oligonucleotide (ASO) based approach designed to provide potent yet reversible suppression of Nav1.7 expression for the treatment of chronic and sub-chronic pain conditions. In parallel, EXG112 also includes an alternative adeno-associated virus (AAV)-based RNA interference (RNAi) modality intended to provide longer-lasting Nav1.7 suppression in selected chronic pain settings. These approaches are being developed as alternative therapeutic options within the EXG112 program, and are intended to offer flexibility across different pain indications while reducing reliance on opioid analgesics.

Chronic pain represents a large and growing global healthcare burden with substantial unmet medical needs. It is estimated that approximately 1.5 billion people worldwide suffer from chronic pain. The global pain management drug market was estimated at approximately US\$81.8 billion in 2025 and is projected to reach approximately US\$110.0 billion by 2030, representing a CAGR of 6.1%, and further grow to US\$143.1 billion by 2035.

The primary EXG112 modality, EXG112-ASO, employs a chemically modified antisense oligonucleotide gapmer designed through the Company's *SODA* platform to selectively degrade Nav1.7 mRNA via RNase H recruitment. Nav1.7 is a genetically validated regulator of nociceptive signaling in peripheral sensory neurons, with loss- and gain-of-function SCN9A mutations causing pain insensitivity and hypersensitivity, respectively, supporting Nav1.7 repression as a non-opioid pain strategy. By reducing Nav1.7 expression in dorsal root ganglion (DRG) neurons and peripheral sensory axons, EXG112-ASO is designed to attenuate pathological pain signaling while maintaining reversibility of effect. The ASO modality is intended to provide therapeutic suppression lasting approximately three to six months following a single administration, supporting use in chronic pain conditions as well as sub-chronic or fluctuating pain settings.

In parallel, the EXG112-AAV modality employs an AAV-delivered microRNA strategy to repress Nav1.7 expression through engagement of endogenous RNA interference pathways. Following a single administration, this approach is designed to provide durable Nav1.7 suppression suitable for selected chronic pain indications that may benefit from long-lasting target modulation. The inclusion of both ASO and AAV modalities supports an indication-tailored development strategy, rather than combination administration, allowing treatment duration and reversibility to be matched to clinical need.

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EXG112 is currently in preclinical development. Studies conducted to date have demonstrated Nav1.7 knockdown with both the ASO and AAV-RNAi modalities, together with reductions in pain hypersensitivity in established rodent pain models, as well as favorable biodistribution to dorsal root ganglion (DRG) tissue and encouraging preliminary safety profiles across species.

The ASO modality is in preclinical lead optimization with ongoing efficacy and safety studies, while the AAV-RNAi modality is advancing through IND-enabling development with ongoing toxicology evaluations. The Company is targeting initiation of a first-in-human investigator-initiated trial in the middle of 2027, with IND submission targeted for the first half of 2029.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG112 SUCCESSFULLY.

EXG111

EXG111 is an adeno-associated virus (AAV)-based gene therapy program under development for the treatment of Duchenne muscular dystrophy (DMD).

EXG111 is designed to deliver a therapeutic micro-dystrophin transgene to skeletal and cardiac muscle tissue with the goal of restoring muscle fiber stability and mitigating disease progression. The micro-dystrophin construct is engineered to retain key functional domains of native dystrophin while remaining within AAV packaging constraints, enabling interaction with dystrophin-associated protein complexes in muscle tissue.

The program is currently in late preclinical development, with IND-enabling activities expected to commence, and IND submission targeted for the second half of 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG111 SUCCESSFULLY.

EXG115

EXG115 is an antibody-oligonucleotide conjugate (AOC) program under development for the treatment of Alzheimer’s disease, a progressive neurodegenerative disorder characterized by substantial unmet medical need. EXG115 is designed to target Tau pathology, which is increasingly recognized as a central driver of neurodegeneration and clinical disease progression in Alzheimer’s disease.

The global Alzheimer’s disease therapeutics market is projected to reach tens of billions of dollars annually. However, currently available therapies generally offer limited clinical benefit, and certain amyloid-targeting antibodies have demonstrated constrained efficacy and safety concerns. In addition, many conventional small-molecule and biologic modalities exhibit limited penetration into the central nervous system, resulting in inadequate exposure and target engagement. Accordingly, there remains a substantial unmet medical need for therapies that effectively address Tau pathology and achieve sufficient central nervous system exposure.

EXG115 is designed to address this unmet need by leveraging our proprietary SODA platform. EXG115 is an antibody-oligonucleotide conjugate intended to enable blood-brain barrier penetration via a TfR1-targeting VHH nanobody, engage and facilitate clearance of extracellular Tau aggregates through an anti-Tau antibody moiety, and reduce Tau production through a chemically modified siRNA payload targeting MAPT mRNA. Through these complementary mechanisms, EXG115 is intended to provide both upstream suppression of Tau expression and downstream engagement of existing Tau pathology, with the goal of improving therapeutic efficacy and durability.

EXG115 is currently in early preclinical development. Planned studies include in vitro and in vivo evaluations of Tau mRNA knockdown, reduction of pathological Tau protein, biodistribution, pharmacokinetics, pharmacodynamics and safety.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG115 SUCCESSFULLY.

EXG116

EXG116 is an adeno-associated virus (AAV)-based gene therapy program under development for the treatment of Rett syndrome, a rare X-linked neurodevelopmental disorder caused by loss-of-function mutations in the MECP2 gene.

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EXG116 is designed to combine a proprietary receptor-targeting AAV capsid (RtAAV001) for systemic central nervous system delivery with a proprietary, multi-layered regulatory expression architecture intended to maintain MeCP2 expression within a physiologically appropriate range.

EXG116 is currently in preclinical development. The Company expects to initiate a first-in-human, investigator-sponsored clinical study designed as an open-label, single-arm, dose-escalation trial primarily focused on safety, immunogenicity and pharmacokinetics, with secondary exploratory measures of efficacy in 2027H2.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG116 SUCCESSFULLY.

EXG113

EXG113 is an adeno-associated virus (AAV)-based gene therapy under development for the treatment of dry age-related macular degeneration (dry AMD), including geographic atrophy (GA). The program is designed to deliver sustained intraocular expression of therapeutic proteins targeting key components of the complement pathway, a central driver of disease progression in dry AMD, with the goal of providing durable disease modification following a single administration.

EXG113 is currently in early preclinical development. Ongoing activities include vector and expression cassette optimization, in vitro validation of complement modulation, and exploratory in vivo studies to assess retinal transduction, pharmacology and safety. Subject to successful completion of these studies, the program is expected to advance into IND-enabling development, including GLP toxicology and biodistribution studies, with the timing of regulatory submission to be determined based on preclinical progress.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXG113 SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

Our Platforms

Focusing on the discovery, optimization, and clinical translation of gene and oligonucleotide-based therapies, we have established a multi-dimensional, systematic core R&D platform system. This primarily includes the AI-aided AAV capsid discovery and engineering system (*AAVarta* platform) and the silencing oligo designing approach (*SODA*) Platform, within which the Antibody-Oligonucleotide Conjugate (AOC) modality represents a key component. These platforms are synergistic, collectively enabling end-to-end advancement across the entire technical pipeline from target identification, vector screening, molecule design, and in vitro/in vivo validation to efficacy and safety evaluation.

AAVarta

The *AAVarta* Platform is a comprehensive, AI-assisted system for the design, screening, and validation of AAV capsids with enhanced tissue tropism and delivery properties. Its integrated, end-to-end workflow enables the rapid evolution of capsids for precise targeting of ocular, muscular, and central nervous system tissues.

Core Architecture & AI-assisted Workflow

The platform’s innovation lies in its deep integration of artificial intelligence across three synergistic technical pillars:

1. Proprietary Data Collection

We construct highly diverse capsid libraries through multi-dimensional strategies, including short/long peptide insertions, site-directed mutagenesis, and data-informed rational design. A proprietary, mRNA recovery-based evaluation system, enables the efficient screening of libraries containing hundreds of millions of variants. Next-Generation Sequencing (NGS) quantifies biological fitness across mice and NHP models, providing high-quality, real-world data to train our AI engine. Then our platform is built on this extensive in-house database derived from multiple rounds of in vivo testing.

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2. *Intelligent In Silico Screening & Evolution*

During screening, we use a bidirectional recurrent neural network (BiRNN) model together with cluster-based sampling to predict and prioritize the most promising variants. This approach allows us to evaluate a much broader, computer-generated sequence space beyond the variants physically included in our experimental library. As a result, we can improve the efficiency and accuracy of our discovery process.

3. *Structure-Based Protein Engineering*

For capsid optimization, we use a step-by-step computational approach. First, we use structure-prediction tools to model how the capsid binds to specific receptors on target tissues (for example, receptors that help cross the blood-brain barrier). We then use a design tool “Rosetta” to suggest rational changes to the capsid, aiming to improve the binding affinity, transduction efficiency, specificity, manufacturability. These improvements are refined through repeated cycles of computer modeling and laboratory testing.

Advanced Module: Receptor-Targeted Capsid Design

Building upon the core platform, this module is dedicated to engineering Receptor-Targeted AAVs (RtAAVs). It employs a structure-guided strategy focusing on human tissue-specific receptors to develop capsids with high transduction efficiency and specificity.

- Target Discovery: A multi-omics database identifies and analyzes tissue-specific receptor targets and their epitopes.
- Directed Library Construction: Generative AI (e.g., RFdiffusion, pepMLM) designs receptor-targeted peptide libraries, which are displayed on AAV capsids.
- Iterative AI-Optimized Screening: A closed-loop system integrates *in vitro* affinity selection with *in vivo* functional validation in non-human primates. The AI prediction model continuously learns from each round, improving screening efficiency and expanding the viable sequence space.
- Cross-Species Validation: Lead candidates undergo systematic validation in rodent and NHP models for efficacy, specificity, and safety.

Platform Output & Validation

The integrated *AAVarta* system has successfully generated multiple novel capsids with validated preclinical and clinical translation:

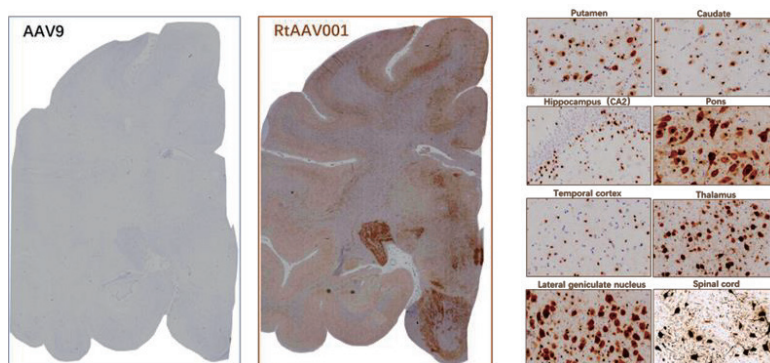
- EOC024: An ILM-penetrating capsid for intravitreal delivery, enabling our retinal gene therapy candidate EXG202.
- RtAAV001: a CNS-targeting capsid engineered for systemic delivery, achieving up to 200-fold greater neuronal transduction efficiency than wildtype AAV9 vectors in nonhuman primates via intravenous injection. This capsid, which forms the foundation of our Rett Syndrome candidate EXG116, transduces 50-70% of neural cells *in vivo* through specific receptor engagement, demonstrating high therapeutic potential for neurodegenerative diseases (see figure below).
- Muscle-Targeted Capsids: Novel muscle-targeting capsids demonstrated up to a 40-fold increase in transgene expression in different muscles of nonhuman primates. This platform-derived capsid has been advanced into our preclinical Duchenne Muscular Dystrophy (DMD) program, EXG111.

This unified platform establishes a scalable engine for discovering optimized AAV vectors, directly addressing translational challenges and creating substantial value across multiple therapeutic areas.

In summary, the RtAAV platform is dedicated to addressing the translational challenges between animal models.

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Strong and Broad CNS Protein Expression in Rhesus monkey



Source: Company in-house data.

SODA

The *SODA* platform focuses on the design of oligonucleotide-based therapeutics that selectively target and silence disease-causing genes, including various molecular modalities such as antisense oligonucleotides, siRNA, miRNA, and AOC. By integrating bioinformatics analysis, target prediction, sequence optimization, chemical modification strategies, and high-throughput in vitro screening, the platform systematically designs candidate molecules with high specificity and potent gene-silencing activity. The specific workflow includes:

(i) **Algorithm-Driven Ranking and Screening:**

Apply machine learning algorithms to rank and optimize candidate small nucleic acid molecules based on binding affinity, knockdown efficacy, off-target characteristics, and chemical stability. In parallel, design chemical modifications to enhance in vivo stability.

(ii) **Cell-Based Validation:**

Synthesize the top 200 candidate small nucleic acid and test their gene-silencing potency in vitro using cell models.

(iii) **In Vitro Stability Assessment:**

Evaluate the stability of chemically modified small nucleic acid in various media, including serum, RNase, cerebrospinal fluid (CSF), and lysosomes.

(iv) **Rodent Validation:**

Select the top 20–30 candidates for testing in mouse or rat models to assess biodistribution, target knockdown efficiency, off-target effects via RNA-seq analysis, and preliminary safety.

(v) **Disease Model Validation:**

Further evaluate the efficacy and in vivo behavior of 5–10 candidates in disease-relevant animal models.

(vi) **Non-Human Primate Evaluation:**

Select the final 2–3 candidates for in vivo administration in non-human primates to observe biodistribution, knockdown efficiency, toxicity, and immunogenicity.

After completing the above systematic validation, candidates confirmed by the Preclinical Candidate Committee (PCC) can proceed to IND-enabling studies. Through this comprehensive workflow, the candidate molecules developed by the *SODA* platform are ensured to demonstrate clear gene-silencing effects in preclinical studies, significant in vivo efficacy, broad tissue distribution, and favorable safety profiles. The results from the current research stage have fully validated the reliability of the *SODA* platform in developing efficient

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gene-silencing therapies and have highlighted its great potential for clinical translation and the development of optimized Oligonucleotide-based therapeutics.

Our R&D Team

Our R&D teams are primarily based in Hangzhou and Guangzhou. The Hangzhou team focuses on the research and development of oligonucleotide-based therapeutics, with an emphasis on sequence design, chemical modification, delivery system optimization, as well as *in vitro* and *in vivo* pharmacodynamic and toxicological evaluation. Meanwhile, the Guangzhou team is mainly dedicated to the clinical development and application of gene therapy products.

As of the Latest Practicable Date, our core research and development team consisted of 22 employees in Hangzhou and 5 employees in Guangzhou, of whom seven hold Ph.D. degrees, 13 hold master’s degrees, and the remaining seven hold bachelor’s degrees or below. Four of them have more than 15 years of experience in gene therapy. Our research and development team is led by our Chief Scientific Officer, Dr. Ye, a leading researcher in the field of gene therapy. He had published over 30 research papers as of the Latest Practicable Date. Members of our research and development team have cross-disciplinary expertise in a variety of fields, including molecular biology, neuroscience, pharmacology & toxicology, vector biology and artificial intelligence. All key R&D personnel involved in the development of the Core Products remained employed by us during the Track Record Period and we believe that they will remain employed by us up to the [REDACTED].

During the Track Record Period, we incurred research and development expenses of RMB145.0 million, RMB103.9 million, RMB57.4 million and RMB53.4 million for the years ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, respectively, which accounted for 87.3%, 85.3%, 87.2% and 76.7% of our total operating expenses (which equals the sum of research and development expenses and administrative expenses), respectively. For details, please see “Financial Information — Significant Factors Affecting our Results of Operations — Our Cost Structure.”.

For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, R&D expenses incurred for EXG102-031 were RMB30.9 million, RMB26.5 million, RMB15.5 million and RMB16.8 million respectively, accounting for 21.3%, 25.5%, 27.1% and 31.5% of our total R&D expenses for the corresponding years. Although our total R&D expenses in 2025 were lower than in 2024, primarily due to decreases in share-based payment, salaries and benefits and depreciation, the trial and testing expenses of EXG102-031 increased by approximately RMB1.6 million for the year ended December 31, 2025 compared with the same period in 2024 mainly because there were more cumulative patient visits in 2025 than in 2024. The R&D expenses for EXG102-031 increased from RMB15.5 million for the six months ended June 30, 2025 to RMB16.8 million for the six months ended June 30, 2026, primarily due to higher labor costs as a result of the grant of ESOP in April 2026.

The following table sets forth a breakdown of research and development expenses attributable to EXG102-031 for the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2024	2025	2025	2026
	RMB'000	RMB'000	RMB'000	RMB'000
Labor costs	13,555	8,998	4,755	8,828
Trial and testing expenses	13,224	14,820	9,360	7,035
Depreciation and amortization	2,546	1,491	853	536
Material costs	309	377	196	84
Power costs	258	142	52	33
Others	967	699	319	278
Total	30,859	26,527	15,535	16,794

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For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, R&D expenses incurred for EXG001-307 (SMA Type 1), one of our Core Products, were RMB42.7 million, RMB30.4 million, RMB16.9 million and RMB11.4 million, respectively, accounting for 29.5%, 29.3%, 29.5% and 21.3% of our total R&D expenses for the corresponding years. The R&D expenses attributable to EXG001-307 are closely correlated with its clinical advancement during the relevant periods. The R&D expenses for EXG001-307 decreased from RMB42.7 million in 2024 to RMB30.4 million in 2025 reflecting differences in clinical development stages and ad hoc manufacturing needs. In 2024, approximately 80% of the main study visits of the patients were completed, corresponding to higher clinical costs in 2024. As of November 30, 2025, the remaining 20% of main study visits had been finished. Since clinical expenses are accrued based on patient visit progress, as such clinical expenditures for this program in 2025 decreased compared with 2024. In addition to the clinical expenses, in 2024, the Company commissioned a new batch of clinical product and recognized related expenses of RMB5.2 million in that year, because previously manufactured clinical supply for the purpose of IND submission had been depleted. As a result, R&D expenses for EXG001-307 for the years ended December 31, 2025 decreased compared to the same period in 2024. The R&D expenses for EXG001-307 decreased from RMB16.9 million for the six months ended June 30, 2025 to RMB11.4 million for the six months ended June 30, 2026, primarily due to reduced labor costs as only follow-up work for a limited number of patients remained in the first half of 2026.

Collaboration with CROs

We perform core functions such as designing clinical development strategies and protocols in-house, and exercise control and oversight over key functions of medical and clinical trial management, including data source validation and analysis of clinical results. In the preclinical stage, we use CROs to conduct in vivo preclinical animal studies. In the clinical stage, we engage CROs to manage, conduct and support our clinical trials.

We select CROs based on various factors, such as their professional qualifications, clinical experience, therapeutic area experience, industry reputation, project specialty, project track record and data management system. In addition, for clinical CROs, we consider their ability to facilitate site selection, timely recruit patients and conduct complex clinical trials efficiently with high quality.

We typically enter into a general service agreement with a CRO under which we execute separate work orders for each clinical development project. We closely supervise these CROs to ensure that they perform in a manner that complies with our protocols and applicable laws and regulations, which in turn protects the integrity and authenticity of the data from our trials and studies.

As of the Latest Practicable Date, we worked with over four CROs. Below is a summary of the key terms of an agreement that we typically enter into with our CROs:

- *Services.* The CRO provides us with services such as the implementation and management of a clinical research project or central laboratory services as specified in the master agreement or a work order.
- *Term.* The CRO is required to perform its services within the prescribed time limit set out in each work order and in accordance with the key performance indicators agreed by both parties.
- *Payments.* We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
- *Risk allocation.* Each party should indemnify the other party for losses caused by its negligence, recklessness, intentional misconduct or material breach of the master agreement or the work order.
- *Intellectual Property.* The intellectual properties generated from the collaboration under the CRO agreements during the term of collaboration shall be solely and exclusively owned by us.

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MANUFACTURING

Our Manufacturing Process

We have established a gene therapy manufacturing process based on large-scale HEK293 cell suspension culture system. This manufacturing process is built on proprietary patented technologies, delivering production efficiency and scalability while ensuring consistent and controllable product quality. Our optimized upstream manufacturing process can achieve high AAV genome titers up to 2×10^{12} vg/mL with a full capsid ratio exceeding 60% for some serotype. Our proprietary booster can improve AAV titers by 4 times at harvest. In the downstream purification stage, our validated two-step chromatography purification process exhibits excellent stability and replicability. Coupled with a comprehensive process control strategy, it achieves an overall downstream recovery yield of over 60%, which is a leading performance metric in the field. In addition, our advanced know-how downstream process significantly reduces the total costs. At 200L GMP scale, our integrated system produces over total 1×10^{17} vector genomes, underscoring the scalability of our manufacturing platform.

Outsourcing the production to CDMO

During the Track Record Period, Hangzhou CoJourney has been providing the manufacturing, testing, and related technical services (the “**CDMO Services**”) to Hangzhou Jiayin. On January 9, 2026, Hangzhou Jiayin entered into a service cooperation agreement (the “**Service Cooperation Agreement**”) with Hangzhou CoJourney, pursuant to which Hangzhou CoJourney agreed to continue to provide the CDMO services to Hangzhou Jiayin. The Service Cooperation Agreement is for a term from January 1, 2026 to December 31, 2028. Please refer to the section headed “Connected Transactions” for details.

We have adopted procedures to ensure that the production qualifications, facilities and processes of our CDMO comply with the relevant regulatory requirements and our internal standards. For example, to monitor and evaluate the services performed by our CDMO, we review all relevant documents and records, especially the manufacturing batch records and quality control records, to ensure that operations of our CDMO are in compliance with relevant procedure requirements. Below is a summary of the key terms of the agreement that we typically enter into with our CDMO:

- *Services.* The CDMO provides us with services such as manufacturing product candidates as specified in individual technology service contract.
- *Term.* The CDMO is required to perform its services within the prescribed time limit set out in each work order and in accordance with the key performance indicators agreed by both parties.
- *Payments.* The CDMO bills us in accordance with milestones agreed by the parties.
- *Risk allocation.* Each party should indemnify the other party for losses caused by its negligence, recklessness, intentional misconduct or material breach of the individual technology service contract.
- *Intellectual property.* We retain intellectual property rights over the plasmid products, production processes, analytical methodologies, and any related improvements that are either provided to the CDMO or developed by the CDMO at our request while the CDMO retains intellectual property rights related to platform technologies, process workflows, testing methods, and other associated technologies involved in the course of providing its services.

REGISTRATION AND INDUSTRIAL COMMUNICATIONS

In the course of the pre-clinical and clinical development of our product candidates, our regulatory affairs team has engaged in communications with relevant regulatory authorities such as the NMPA and the FDA. As of the Latest Practicable Date, we had not received any material concerns, objections or negative statements raised by the NMPA, the FDA, or other relevant authorities that we are not able to address in a timely manner.

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The following table sets forth material communications we had with regulatory authorities during our research and development of EXG102-031 and EXG001-307 (SMA Type 1), our Core Products, as well as EXG202, our Key product:

EXG102-031

Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA	Type II	Pre-IND Meeting	October 12, 2022	Sought recommendation from NMPA on the requirements for IND of EXG102-031 for the treatment of wAMD	NMPA provided written feedback on the questions across all disciplinary areas.
NMPA	IND submission	IND submission	March 8, 2023	Initial IND Application in China	Initial IND Application was approved
Yangtze River Delta-NMPA	Face-to-Face Symposium	Face-to-Face Symposium	May 22, 2025	Consulted on Phase III Trial Protocol Design	Yangtze River Delta-NMPA advised on the application timeline and primary endpoint selection
U.S./FDA	Type B	Pre-IND Meeting	August 22, 2022	Sought the inputs on the development program for EXG102-031	FDA provided written responses to all questions
U.S./FDA	IND submission	IND submission	December 16, 2022	Initial IND Application in US	Study may proceed
U.S./FDA	Type C	Supplementary ⁽¹⁾ study	March 30, 2023	Sought the feedback and confirmation on GLP Toxicology study proposed to provide additional nonclinical data to support higher clinical dose	FDA provided Written Responses to the questions about the GLP toxicology study protocol
U.S./FDA	Type D	Protocol amendment ⁽¹⁾	February 9, 2024	Discussed the results of a supplementary NHP study with the desire to receive the feedback prior to submitting future information and protocol amendments to the active protocol	FDA approved the higher dose in the protocol

EXG001-307 (SMA Type 1)

Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA	Type II	Pre-IND Meeting	October 28, 2021	Sought recommendation from NMPA on the requirements for IND of EXG001-307 for the treatment of SMA Type I	NMPA provided written feedback on the questions across all disciplinary areas.
NMPA	IND submission	IND submission	March 25, 2022	Initial IND Application for the treatment of SMA Type I	Initial IND Application was approved

Note:

- (1) The supplementary study and protocol amendment did not affect the original trial design of EXG102-031 or constitute additional work/conditions imposed by the relevant authorities that have to be completed prior to the completion of the Phase I clinical trial and progression to the next phase of clinical trial.

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Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA	Type I	Protocol amendment ⁽¹⁾	February 7, 2024	The study plans to enroll rollover subjects from the EXG001-307-102 trial who have previously received risdiplam treatment, have completed the washout period, and have not achieved the ability to sit independently. The trial will maintain a single-arm design, using natural history data as the control	Per regulatory guidance, the submission of a supplemental application is required for any change that could potentially increase subject safety risks.
NMPA	Type I	Pre-IND Meeting	April 11, 2025	Sought recommendation from NMPA on the IND requirements for IND of EXG001-307 Intrathecal injection for the treatment of SMA Type 2 and Type 5	NMPA provided written feedback on the questions across all disciplinary areas.
U.S./FDA	Type B	Pre-IND Meeting	July 1, 2024	To receive agency input on product, pre-clinical, and clinical issues for Phase I and the overall drug development program	FDA provided written responses to questions and an additional videoconference discussion on clinical questions was held

EXG202

Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA	Type II	Pre-IND Meeting	January 22, 2025	Sought recommendation from NMPA on the clinical trial strategy for developing EXG202 Injection for the treatment of wAMD	NMPA provided written feedback on the questions across these disciplinary areas.
NMPA	IND submission	IND submission	May 12, 2025	Initial IND Application	Initial IND Application was approved
U.S./FDA	IND submission	IND submission	June 9, 2025	Initial IND Application	Study may proceed

EXG110

Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA	Type II	Pre-IND Meeting	April 27, 2024	Sought advice from NMPA on the clinical development plan for EXG110 Injection in Fabry in China, as well as on issues pertaining to pharmacology, toxicology, CMC and clinical disciplines	NMPA provided written feedback on the questions across these disciplinary areas.

Note:

- (1) The protocol amendment did not affect the original trial design of EXG001-307 (SMA Type 1) or constitute additional work/conditions imposed by the relevant authorities that have to be completed prior to the completion of the Phase I clinical trial and progression to the next phase of clinical trial.

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Regulatory Authority	Communication Type	Form of Communication	Date	Content of Communication	Results of Communication
NMPA/CDE . . .	IND submission	IND submission	September 12, 2024	Initial IND Application	Initial IND Application was approved
U.S./FDA . . .	Orphan Drug Designation Request	Orphan Drug Designation Request	August 13, 2024	Orphan Drug Designation Request for EXG110 for the treatment of Fabry disease.	Designated

In addition to communications with the regulatory agencies by our regulatory affairs team, in the course of clinical trials of our product candidates, we have engaged in close communications with principal investigators and ethics committees at the clinical sites at which we conducted our clinical trials. We received approval for our proposed clinical trials at such clinical sites from the relevant ethics committees. For further information on the data that we gathered from our clinical trials, see “— Our Product Pipeline.”

As a result of the foregoing communications, we developed extensive training materials for physicians on the administration of our product candidates, as well as a comprehensive introduction to gene therapy for patients as part of the process of obtaining informed patient consent to the administration of our product candidates. We expect that our communications with physicians at the hospitals and research institutes where we conducted clinical trials of our product candidates will contribute to the formation of our commercialization strategy for product candidates once they are approved by relevant regulatory authorities. As these institutions have established treatment or disease management procedures and supporting medical resources developed during the administration of our product candidates as part of our clinical trials, these institutions are expected to also be our initial commercial target sites. For additional information on our commercialization plan, see “— Commercialization.”

Aside from the foregoing material regulatory and industrial communications, we do not believe that our communications with other third parties (such as key opinion leaders, patient groups, consultants or scientific advisors) had a material impact on the design of our clinical trial plans or commercialization plans with respect to our product candidates. We have regularly updated our shareholders on the implementation of our clinical development plan.

DATA PRIVACY AND PROTECTION

In the course of the Group’s clinical development and operations, the personal data collected primarily falls into the following categories:

- (i) **Identification information of participants:** directly identifiable information such as name, identification number, contact details, residential address, gender and age;
- (ii) **Health and medical data:** medical history, diagnostic results and prior medical history/medication history; and
- (iii) **Clinical trial-related data:** records of informed consent execution, medical records generated during trial participation, adverse event and concomitant medication records, laboratory test data, imaging materials and diary cards of participants.

All data processing is conducted in compliance with the Personal Information Protection Law of the PRC and adheres to the “minimum necessary” principle. We implement de-identification or anonymization measures as appropriate. The original source documents relating to the above information are properly maintained at each study site. As the sponsor of the clinical trials, we generally access and review relevant data through an electronic data capture system, in which the data has been de-identified.

The permitted scope of use of the above personal data is strictly limited to the following purposes:

- (i) **Drug R&D and regulatory filings:** to support submission of clinical trial data for new drug applications to the NMPA and/or FDA, and to satisfy applicable requirements under ICH-GCP and the *Administrative Measures for Drug Registration*;

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- (ii) **Efficacy and safety assessment:** following de-identification, for statistical analyses and risk/benefit assessments; and
- (iii) **Compliance audits and regulatory inspections:** for review by drug regulatory authorities and audit institutions to verify the authenticity and integrity of the underlying data.

As advised by our PRC Legal Adviser and U.S. Legal Adviser and based on the due diligence conducted by our U.S. Legal Adviser in connection with the [REDACTED], such collection and use of personal data comply with material applicable laws and regulations concerning data privacy and security in China and the United States during the Track Record Period and up to the Latest Practicable Date.

To safeguard the security of such personal data, we have adopted the following internal control measures and policies:

1. **Technical safeguards.** Clinical data is collected and managed through an electronic data capture (“EDC”) system. Access to the relevant data is restricted to authorized personnel only. Audit trail functionality is enabled for each EDC system, recording the time, operator and reasons for any data modifications. Our EDC servers for all China trials are deployed within the PRC.
2. **Training.** Our clinical operations personnel, including clinical trial assistants, clinical research associates, project managers and clinical directors, have received GCP training and obtained relevant certificates. They are familiar with applicable requirements on clinical trial data management, personal information protection and GCP, and conduct their work in accordance with relevant laws, regulations and requirements.
3. **Third-party management.** We conduct onboarding and due diligence reviews of third parties such as CROs and cloud service providers, require them to obtain ISO 27001 certification, and enter into confidentiality agreements with them.

We currently have no record of cross-border data transfers. If cross-border data transfers are involved in the future, we will implement relevant arrangements in accordance with the *Provisions on Promoting and Regulating Cross-border Data Flows* (《促進和規範資料跨境流動規定》). Where the export of human genetic resources information (such as genomic data) is involved, we will make the requisite filings with, and obtain approval from, the Ministry of Science and Technology in accordance with the *Regulations of the PRC on the Administration of Human Genetic Resources* (《中華人民共和國人類遺傳資源管理條例》), and maintain relevant records.

We have not experienced any incident of patient data or other personal data leakage or material losses during the Track Record Period and up to the Latest Practicable Date.

COMMERCIALIZATION

Commercial Viability

We believe our Core products and Key Product are commercially viable for the following reasons:

- (i) there is high unmet clinical needs for SMA treatment and fundus neovascularization diseases treatment, including wAMD;
- (ii) compared to other product candidates, one of our Core Products, EXG102-031, offers durable single-dose therapy that delivers multi-angiogenic pathway inhibition via subretinal delivery, alleviating the burden associated with frequent injections of anti-VEGF biologics and overcoming the limitations of pre-existing anti-AAV neutralizing antibodies in the circulation. Our other Core Product, EXG001-307 (SMA Type 1), offers a neuron-targeted, durable gene therapy with reduced systemic exposure and improved safety compared with existing therapies, addressing both biological and real-world challenges. Our Key Product, EXG202, offers a durable, single-injection therapy that overcomes limitations of current anti-VEGF treatments. Advanced gene therapy capsid that efficiently transduces

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retinal and RPE cells following intravitreal injection, ensuring therapeutic efficacy, reducing dosing and surgical burden, and greatly expanding eligible patient population.

- (iii) our Core Products and Key Product have demonstrated favorable safety and efficacy results from our clinical trials; and
- (iv) our competitive edge in Core Products and Key Product is protected by our patent portfolio. See “— Intellectual Property Rights.”

Our Marketing Strategy

We plan to launch our Core Products EXG102-031 and EXG001-307 (SMA Type 1) and our Key Product EXG202 in 2032, 2030 and 2032, respectively.

We will employ a strategic marketing model to increase our market penetration, to promote our products and to achieve geographical and channel coverage. We plan to conduct marketing activities in China first, and as our operations mature, we intend to expand our marketing activities in the United States and other regions with high unmet needs. We expect to facilitate academic engagement and education around our products by establishing relationships with KOLs, hospitals, and renowned doctors through clinical trials, R&D collaboration, and academic conferences.

In addition, our strategy includes a phased approach to entering all levels of markets, aiming for comprehensive national reach over the medium term. Initially, our efforts will be directed towards the top hospitals in top and second tier provinces that possess a significant patient population. As we progress into tier three and four provinces, our commitment to enhancing our local presence and market penetration will persist. We aim to cooperate with regional agents in business development at hospitals and fortify our connections with pivotal stakeholders in each province to promote diagnosis and treatment, as well as to facilitate negotiations for reimbursement inclusion in the national medical insurance reimbursement catalog. In particular, we plan to begin considering the reimbursement inclusion of our products in the national medical insurance reimbursement catalog after three years from the launch of the relevant products into the market. Through these measures, we believe we will expand the market share of our Core Products and Key Product in China.

Along with the clinical development of our pipeline products, we will establish our marketing center, including sales, marketing and business departments and schedule the recruitment, training and evaluation of our sales and marketing team in accordance with the clinical development progress of our pipeline products, aiming to ensure the timely commercialization of our pipeline products once we obtain relevant approvals.

Pricing

As of the Latest Practicable Date, our Core Products and Key Product were still in the clinical trial phase and had not been commercialized. As such, we have not established any definitive pricing policy for our Core Products and Key Product. As our Core Products and Key Product progress towards potential approval and commercialization in the future, either we or a partner will determine pricing by evaluating multiple factors, including the clinical attributes of our Core Products and Key Product and the existing market prices of other comparable drugs. We or a partner may conduct extensive market research involving KOLs, hospitals, physicians and patients as well as regulatory authorities before pricing our Core Products and Key Product and may take into account various factors such as insights gathered from these parties, our production costs, the comparative safety and efficacy of our Core Products and Key Product against its competing products, the estimated demand for our Core Products and Key Product and their clinical value to patients. For pricing in China, we or a partner may determine pricing based on the affordability for local patients and the price of comparable products. The pricing in overseas markets may be adjusted to reflect the unique market conditions of each region, which includes the pricing strategies of multinational competitors. With expectations of higher drug pricing and market demand, we anticipate the revenue from sales of our Core Products and Key Product to be substantially higher than its associated R&D costs.

SUPPLIERS AND RAW MATERIALS

During the Track Record Period, the principal raw materials that we used in our business consist of consumables for various instruments, such as PCR machines, centrifuge

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tubes, among others. We had engaged service providers such as CDMOs and CROs primarily to support our clinical trials in China and the United States and to produce our product candidates.

Our purchases from our five largest suppliers in each period during the Track Record Period amounted to RMB30.4 million, RMB14.9 million and RMB8.3 million, representing 61.0%, 45.7% and 51.0% of our total purchases for the respective periods, and our purchases from our largest supplier alone in each period during the Track Record Period accounted for 29.4%, 22.7% and 29.2% of our total purchases, respectively. Purchases primarily included third-party contracting services for research and development purposes, raw materials, equipment, construction and management services. Except for Hangzhou CoJourney, all of our five largest suppliers during the Track Record Period are Independent Third Parties. Save for Dr. Wu, Dr. Ye and Ms. Wang, each of whom is indirectly interested in the equity of Jiaxing CoJourney, none of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period. For details, see “Relationship with Controlling Shareholders — Other Business or Interest of Controlling Shareholders” in this document.

The following table sets forth the details of our top five suppliers for the six months ended June 30, 2026:

Rank	Supplier	Background	Main Products/Services Provided	Purchase Amount <i>(RMB in thousand)</i>	Percentage of Total Purchase <i>(%)</i>	Business Relationship Since
1	Supplier A	A CRO company based in US, specializing in providing clinical trial services to biotechnology companies.	CRO services	4,757	29.2	2023
2	Hangzhou CoJourney	A CDMO company, based in China, providing customized services including process development for plasmid, viral vector and mRNA preparation, cGMP production, analytical method development and product testing and release.	CDMO services	1,451	8.9	2023
3	Supplier C	A clinic based in US, providing diagnosis and treatment services for eye diseases and conducts clinical research on retinal diseases as a clinical research center.	Clinical center services	710	4.4	2023
4	Supplier B	A tertiary-level Class A general hospital, based in China.	Clinical center services	708	4.3	2023
5	Moslet (Hangzhou) Biotechnology Co., Ltd. (莫斯萊特(杭州)生物技術有限公司)	A CRO company based in China, providing services including laboratory animal model development, animal experiment protocol design and implementation, and laboratory animal husbandry to biotechnology companies.	CRO services	683	4.2	2022
Total . .				8,309	51.0	

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The following table sets forth the details of our top five suppliers for the year ended December 31, 2025:

Rank	Supplier	Background	Main Products/ Services Provided	Purchase Amount <i>(RMB in thousand)</i>	Percentage of Total Purchase <i>(%)</i>	Business Relationship Since
1	Supplier A	A CRO company, based in US, specializing in providing clinical trial services to biotechnology companies.	CRO services	7,417	22.7	2023
2	Hangzhou CoJourney	A CDMO company, based in China, providing customized services including process development for plasmid, viral vector and mRNA preparation, cGMP production, analytical method development and product testing and release.	CDMO services	2,150	6.6	2023
3	Jiangsu Dingtai Pharmaceutical Research (Group) Co., Ltd.* (江蘇鼎泰藥物研究(集團)股份有限公司)	A CRO company, based in China, providing comprehensive non-clinical safety, efficacy, and DMPK studies, as well as integrated clinical trial services from proof-of-concept to pivotal trials.	CRO services	2,043	6.3	2021
4	WestChina-Frontier Pharmatech Co., Ltd.* (成都華西海圻醫藥科技有限公司)	A CRO company, based in China, providing toxicology research technical services.	CRO services	1,786	5.5	2023
5	Supplier B	A tertiary-level Class A general hospital, based in China	Clinical center services	1,514	4.6	2023
Total . . .				14,910	45.7	

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The following table sets forth the details of our top five suppliers for the year ended December 31, 2024:

Rank	Supplier	Background	Main Products/ Services Provided	Purchase Amount <i>(RMB in thousand)</i>	Percentage of Total Purchase <i>(%)</i>	Business Relationship Since
1	Hangzhou CoJourney	A CDMO company, based in China, providing customized services including process development for plasmid, viral vector and mRNA preparation, cGMP production, analytical method development and product testing and release.	CRO services	14,659	29.4	2023
2	Supplier A	A CRO company, based in US, specializing in providing clinical trial services.	CRO services	6,709	13.4	2023
3	Guoke Safebo Pharmaceutical Technology (Hebei) Co., Ltd.* 國科賽賦河北醫藥技術有限公司	A CRO company, based in China, providing preclinical and non-clinical pharmacology and toxicology CRO research services for drugs.	CRO services	4,375	8.8	2023
4	Jiangsu Dingtai Pharmaceutical Research (Group) Co., Ltd.* 江蘇鼎泰藥物研究(集團)股份有限公司	A CRO company, based in China, providing comprehensive non-clinical safety, efficacy, and DMPK studies, as well as integrated clinical trial services from proof-of-concept to pivotal trials.	CRO services	2,544	5.1	2021
5	Children’s Hospital of Fudan University* 復旦大學附屬兒科醫院	A tertiary-level Class A comprehensive children’s hospital, based in China	Clinical center services	2,151	4.3	2022
Total . .				30,438	61.0	

COMPETITION

Our industry is highly competitive and subject to rapid and significant change. We face potential competition from many different sources working to develop therapies targeting the same indications against which we are developing our drug candidates. These include major pharmaceutical companies, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future.

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EMPLOYEES

The following table sets forth a breakdown of our employees by function as of the Latest Practicable Date:

Function	Number	Percentage
Research	27	39%
Clinical development	16	23%
Process development	9	13%
Finance/Legal/HR/IT/Others	17	25%
Total	69	100.0%

As of the Latest Practicable Date, we had 67 employees in China and two employees in the United States. We enter into standard confidentiality and employment agreements with our key management and research staff. Our employees’ remuneration consists of salaries, bonuses, share-based incentive plans, social insurance contributions and other welfare payments. In accordance with applicable laws, we have made contributions to social insurance funds and housing funds for our employees. We conduct new staff training regularly to guide new employees and help them adapt to the new working environment.

We believe that we maintain a good working relationship with our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial action which had a material effect on our business. We believe we have not experienced any significant difficulty in recruiting staff for our operations.

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we (i) owned six issued patents in China and one issued patent in Macao, and (ii) filed ten published patent applications in China, 16 published PCT patent applications that are currently active, and 14 published patent applications in the U.S. and other jurisdictions relating to certain of our product candidates and platform technologies. Our intellectual property counsel, conducted a freedom-to-operate (FTO) analysis based on patents, patent applications and PCT applications published in the PRC and the United States on or before June 30, 2026, subject to the on-going or planned clinical trials and the projected commercialization territories confirmed by the Company. As of the Latest Practicable Date, our Directors believe that we have not infringed any IP rights of third parties. The following table summarizes the details of the material granted patents and filed patent applications by our Company in connection with our clinical and preclinical product candidates:

Product	Scope of Patent Protection	Status	Inventors/ owners	Patent expiration ⁽¹⁾	Jurisdictions
EXG001	A viral packaging plasmid and its application	Granted	Inventors: Zhongwan Li, Shuyuan Chen, Qian Guo, Guojie Ye, Zhenhua Wu Owner: Hangzhou Jiayin	2044	China

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Product	Scope of Patent Protection	Status	Inventors/ owners	Patent expiration ⁽¹⁾	Jurisdictions
EXG001	Nucleic acid constructs and their use in the treatment of spinal muscular atrophy	Granted	Inventors: Peixin Zhu, Guojie Ye, Zhenhua Wu, Lijun Wang Owner: Hangzhou Jiayin	2041	China
EXG001	NUCLEIC ACID CONSTRUCTS AND USES THEREOF FOR TREATING SPINAL MUSULAR ATROPHY	Pending	Inventors: Peixin Zhu, Guojie Ye, Zhenhua Wu, Lijun Wang Owner: Hangzhou Exegenesis		Canada, Australia, Japan, Israel, Republic of Korea, European Patent Office, USA
EXG001	Construction and application of induced stable cell lines with downregulated endogenous SMN	Granted	Inventors: Li Dai, Ye Zhang, Shai Huang, Guojie Ye, Zhenhua Wu Owner: Hangzhou Jiayin	2044	China
EXG102	Fusion molecules targeting VEGF and angiopoietin and their applications	Granted	Inventors: Guojie Ye, Zhenhua Wu, Lijun Wang, Li Dai Owner: Hangzhou Jiayin	2042	China
EXG102	FUSION MOLECULES TARGETING VEGF AND ANGIOPOIETIN AND USES THEREOF	Pending	Inventors: Guojie Ye, Zhenhua Wu, Lijun Wang, Li Dai Owner: Hangzhou Exegenesis		Canada, Australia, Japan, Israel, Republic of Korea, European Patent Office, USA
EXG202	AAV2 Packaging Plasmids and their applications	Pending	Inventors: Zhongwan Li, Shuyuan Chen, Qian Guo, Jiahao Xu, Bifeng Chen, Guojie Ye, Zhenhua Wu, Lijun Wang Owner: Hangzhou Jiayin		China
EXG202	A NOVEL AAV VARIANT	Pending	Inventors: Shuyuan Chen, Zhenhua Wu, Guojie Ye, Shaoyong Li, Zhongwan Li Owner: Hangzhou Jiayin, Exegenesis Bio Co., Exegenesis Bio Singapore Pte. Ltd		N/A

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Product	Scope of Patent Protection	Status	Inventors/ owners	Patent expiration ⁽¹⁾	Jurisdictions
EXG202	A Novel Intravitreal Gene Therapy for neovascular diseases	Pending	Inventors: Guojie Ye, Shuyuan Chen, Li Dai, Zhenhua Wu, Zhongwan Li, Ye Zhang Owner: Hangzhou Jiayin, Exegenesis Bio Co., Exegenesis Bio Singapore Pte. Ltd		N/A
Platform (AAVarta) .	Transferrin receptor binding polypeptide-incorporated capsids and the uses thereof	Pending	Inventors: Zhenhua Wu, Jingbo Liu, Shaoyong Li, Guojie Ye, Owner: Exegenesis Bio Co., Hangzhou Jiayin, Hangzhou Exegenesis, Exegenesis Bio Singapore Pte. Ltd		N/A
Platform (AAVarta) .	An improved method of producing AAVs incorporated with large polypeptides	Pending	Inventors: Zhenhua Wu, Jingbo Liu, Shaoyong Li, Guojie Ye, Xin Xin Owner: Exegenesis Bio Co., Hangzhou Exegenesis, Hangzhou Jiayin, Exegenesis Bio Singapore Pte. Ltd		N/A
Platform (AAVarta) .	AAV VARIANTS AND USES THEREOF	Pending	Inventors: Shuyuan Chen, Zhenhua Wu, Guojie Ye, Shaoyong Li, Zhongwan Li Owner: Hangzhou Jiayin		N/A

Notes:

- (1) Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

We conduct our business under the brand name of “Exegenesis”. As of the Latest Practicable Date, we had registered 12 trademarks in China, and have registered one trademark in Hong Kong. We are also the registered owner of two domain names.

As of the Latest Practicable Date, save as disclosed in this document, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

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AWARDS AND RECOGNITIONS

The following table sets forth some of the important accreditations and awards we have received from the relevant authorities and organizations in China during the Track Record Period in recognition of our research and development capabilities:

Year	Accreditation/Award	Accreditation Organization
2024	2024 Hangzhou’s Quasi-Unicorn Enterprises	Hangzhou Venture Capital Association
2023	The R&D project “Key Research and Development Program of Zhejiang Province, China” was selected as part of the 2023 “Leading Goose” Key R&D Program	Zhejiang Provincial Department of Science and Technology
2023	Zhejiang Provincial Postdoctoral Research Station	Zhejiang Provincial Department of Human Resources and Social Security
2022	The “Gene Therapy Drug R&D and Industrialization Innovation Team” was selected as a “Leading Innovation and Entrepreneurship Team in Hangzhou” in 2022	Hangzhou Science and Technology Bureau
2021	Outstanding Enterprises and Second Prize of the 10th China Innovation and Entrepreneurship Competition	Ministry of Science and Technology
2021	Hangzhou “Young Eagle Plan” Enterprises	Hangzhou Science and Technology Bureau

LAND AND PROPERTIES

According to Section 6(2) of the Companies Ordinance (Exemption of Companies and prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong) and Chapter 5 of the Listing Rules, this document is exempted from compliance with the requirements of Section [REDACTED] of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which require a valuation report with respect to all of our interests in land and buildings, for the reason that, as of June 30, 2026, we had no property interest with a carrying amount of 15% or more of our total assets.

Leased Properties

As of the Latest Practicable Date, we leased two properties in China for use as our laboratories and offices with an aggregate GFA of approximately 6,391.1 sq.m. and two properties in the U.S. for use as our laboratories and offices with an aggregate GFA of approximately 344.14 sq.m. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration.

BUSINESS

ENVIRONMENTAL, SOCIAL AND GOVERNANCE (“ESG”) MATTERS

ESG Governance

Led by the Board, we are committed to integrating ESG considerations into our business operations. The Board has the overall responsibility for overseeing ESG strategy, management approach, policies and performance, including ESG-related risks and opportunities (particularly climate-related matters), and reviews progress against relevant metrics and targets to ensure alignment with our long-term development.

To support the Board’s oversight, we have established an ESG working group comprising senior management and heads of major functional departments. Delegated by the Board, the ESG working group is responsible for coordinating ESG- and climate-related matters across our Group. Key responsibilities of the ESG working group include: (i) assessing the effectiveness of the ESG management framework and structure of the Group and advising on any necessary changes; (ii) monitoring the Group’s performance against its goals and targets; (iii) monitoring stakeholder’s feedback (including the review and approval of material issues and materiality matrix); (iv) identifying and advising the Board on significant ESG and climate-related risks and opportunities and corresponding action plans; (v) supervising the ESG-related functional departments to advance the Group’s sustainability agenda; and (vi) reviewing and approving the annual ESG report of the Group. The ESG working group reports to the Board at least once a year on ESG performance, key risks and opportunities, and the implementation status of related measures. The Board retains the ultimate oversight responsibility for our ESG risk management.

Materiality Assessment

The materiality assessment plays an important role in advancing our ESG strategy and forming the foundation for ESG disclosure. Upon [REDACTED], we will adopt a three-step approach to identify, prioritise and validate ESG issues material to our business and stakeholders, allowing us to gain insights of stakeholders’ expectations and emerging sustainability trends. This in turn enables us to incorporate our sustainability priorities into our strategy development and reporting processes:

Step 1 – Identification

- (i) Review and summarise potential material ESG issues identified through regular stakeholder engagement; (ii) conduct peer benchmarking and make reference to international ESG disclosure standards and the materiality maps proposed by reputable ESG ratings agencies, including the Sustainability Accounting Standards Board (“SASB”) Standards, IFRS S1 General Requirements for Disclosure of Sustainability-related Financial Information (“IFRS S1”), IFRS S2 Climate-related Disclosures (“IFRS S2”), and MSCI’s ESG Industry Materiality Map; and (iii) conduct an online stakeholder engagement survey with key external and internal stakeholders including customers, employees, suppliers, investors and management.

Step 2 – Prioritisation

- (i) Assess material ESG issues from two perspectives: stakeholder materiality (importance to stakeholders) and financial materiality (importance to business performance continuity and development); and (ii) develop a materiality matrix based on the findings from the online stakeholder engagement survey.

Step 3 – Review and validation

- Present the list of identified material issues and the materiality matrix to ESG working group for review and approval

BUSINESS

Identification and Management of ESG-related Risks and Opportunities

We conduct periodic assessments to identify, assess and prioritize material ESG-related risks and opportunities relevant to our business, either negative or positive, actual or potential, taking into account our business nature, industry characteristics, and with reference to local and international reporting frameworks. With the assistance of third-party ESG consultants, we formulate a dual ESG-related risks and opportunities rating system to dynamically monitor and assess both the risks and the effectiveness of our corresponding mitigation measures. We assess identified ESG risks and opportunities by assigning initial risk ratings based on their likelihood and potential impact on our business, strategic, and financial performance. We then implemented corresponding mitigating measures and determined residual risk ratings after taking into account the effectiveness of our ESG-related risk control measures.

Set forth below is a summary of identified material ESG-related risks and opportunities and the corresponding measures that have been formulated.

ESG-related risks	Timeframe and potential impacts	Mitigating actions (adopted/to be adopted)	Quantifiable risk indicators
Climate-related physical risks			
Acute risks: The increased severity and frequency of extreme weather events due to climate change (e.g., typhoons, rainstorms, floods)	Short, medium and long term <ul style="list-style-type: none"> • Damage to property and assets in our operating locations, which may adversely impact our financial results • Disruption to business operation and supply chain and logistics arrangement • Minor raw material delivery delays in affected areas during extreme weather 	<ul style="list-style-type: none"> • We have closely monitored the local weather forecasts and reminded our staff to remain familiar with business contingencies as well as implementing emergency protective measures. • We will consider prioritising the selection of local and nearby suppliers 	For our greenhouse gas (“GHG”) emissions, please refer to the “Environmental Metrics and Targets”
Climate-related transition risks			
Policy and legal risks: Evolving climate-related laws and regulations in transition to a low-carbon economy, including China’s 2060 carbon neutral goal	Medium to long term <ul style="list-style-type: none"> • Increase in compliance and operating costs 	<ul style="list-style-type: none"> • We regularly and closely monitor the latest changes in laws, policies and regulations • We promptly communicate the policy updates to our employees to ensure compliance • We will assess the feasibility of implementing new climate-related disclosure requirements and, where applicable, develop transition measures in line with more ambitious policies and regulations 	For our GHG emissions, please refer to the “Environmental Metrics and Targets”

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ESG-related risks	Timeframe and potential impacts	Mitigating actions (adopted/to be adopted)	Quantifiable risk indicators
Other ESG-related risks			
Supply chain risks: Energy consumed and greenhouse gas (“GHG”) emissions released along the supply chain	Short, medium and long term <ul style="list-style-type: none"> Increase in reputational and operational risks Increase in administrative cost and resource allocation in data collection from key suppliers for scope 3 GHG emissions reporting 	<ul style="list-style-type: none"> We encourage our suppliers to explore opportunities to reduce environmental impact within their daily operations and manufacturing processes We have established policies which require suppliers to comply with environmental laws and regulations, as well as minimizing energy consumption where possible We will closely monitor regulatory developments and, where applicable, work with key suppliers to enhance energy efficiency and GHG emissions performance 	Upon the [REDACTED], we will enhance our scope 3 data collection system to strengthen carbon emissions tracking and management across key suppliers
Supplier product quality and supply chain stability risks: Failure to meet customer expectations due to poor supplier product and service quality, and poor supply chain stability	Short, medium and long term <ul style="list-style-type: none"> Increase in reputational risks, which may adversely impact our financial results 	<ul style="list-style-type: none"> We have established a supplier management policy to specify the supplier evaluation process, review frequency and criteria. This includes the consideration of suppliers’ product quality and the ability to deliver goods in a timely manner We will maintain stable partnerships with key suppliers and regularly review their relevant qualifications and certifications 	We will conduct an annual key supplier performance evaluation covering indicators such as product quality, supplier stability, and on-time delivery
Climate-related opportunities			
Markets: Increasing marketing demand for specific medical treatments driven by the impact of climate change on human health, such as worsening central nervous system conditions due to extreme high temperatures	Medium to long term <ul style="list-style-type: none"> Increase in operating revenue driven by growing market demand and health needs 	<ul style="list-style-type: none"> We continuously conduct R&D and regular market research We will focus on talent development by providing product innovation training, ensuring employees stay informed about the latest health trends 	N/A

BUSINESS

ESG Policy

We are committed to incorporating ESG factors into our business decision-making process. As such, we have established a group-level ESG policy complemented by a set of measures and initiatives to guide our actions and measures to strengthen our sustainability efforts.

Environment

Our environmental policy outlines our green practices and measures (as far as practicable), with a focus on emission reduction, waste reduction (including wastewater management), resource conservation, protection of environmental and natural resources, as well as addressing climate change.

Energy, Air and Greenhouse Gas Emissions Management

The major sources of our energy consumption and GHG emissions (Scope 2) include the use of purchased electricity, steam and cooling. We have implemented policies and energy saving measures, including the adoption of energy efficient equipment and LED lighting system, the use of natural light, requiring employees to turn off idling electrical equipment.

The major sources of air emissions are exhaust gases generated from our laboratory operations, including hydrogen chloride (“HCl”) and non-methane hydrocarbons (“NMHCs”). We have established policies to manage such emissions through designated exhaust and treatment systems, including activated carbon adsorption and high-efficiency filtration, with emissions discharged via purified ventilation systems. Designated personnel conduct regular inspections of the exhaust treatment systems and arrange timely maintenance and replacement of adsorbents, such as activated carbon and sodium hypochlorite, where necessary. Qualified third parties are also engaged to conduct regular monitoring in accordance with applicable environmental requirements. We are continuously exploring measures to minimise air emissions, including ensuring the proper maintenance of company vehicles and considering the adoption of electric vehicles.

Water Consumption

Our water consumption mainly arises from municipal water usage in operations. We have implemented water saving measures, including timely repair of water leaks, adoption of water-efficient fixtures, water consumption monitoring, and internal communications to encourage employees to reduce water usage.

Waste Management and Use of Resources

Non-hazardous waste mainly comes from general refuse while hazardous waste primarily includes laboratory waste liquids, waste filter cartridge and waste chemical packaging during R&D and experimental procedures. We ensure proper handling and disposal of all waste and, where necessary, engage licensed third-parties for collection and treatment. Hazardous waste will be stored, classified and recorded in designated areas and containers, and handled by licensed service providers. Storage facilities are equipped with appropriate containment and protection measures, including weatherproofing, spill prevention and leakage collection systems, to mitigate environmental risks. Designated personnel oversee hazardous waste management. In respect of wastewater management, we have established policies and operate an on-site wastewater treatment facilities to ensure compliance with the relevant standards, with wastewater undergoing separate treatment processes, including biochemical reactions, prior to discharge. We conduct routine inspections of wastewater treatment facilities, with any irregularities promptly addressed. We also maintain online monitoring systems and engage qualified third parties to conduct periodic wastewater discharge testing to ensure compliance with applicable standards.

BUSINESS

To minimize non-hazardous waste, we promote waste sorting and recycling, implement double-sided printing and remind employees to minimize waste through internal communications. Regular staff training and emergency drills are conducted, and contingency measures and response plans are in place for potential incidents.

Environmental Metrics and Targets

With reference to our historical environmental performance, our expected business operational scale and the expected measures to be implemented in the future, we have set targets to support the national “30•60” carbon peak and neutrality targets, as well as international standards such as the Paris Agreement, with the timeframe of our targets established with reference to such national and international standards. To advance our commitment to environmental protection, we have established the following reduction target by 2030, using 2024 as the baseline, with the assumption of constant related emission factors and considering future business operations. For details of measures implemented to achieve these targets, please refer to “Environment” in this section.

- Reduce GHG emissions (Scope 2) intensity (tCO₂e /gross floor area (“GFA”) (m²)) by 5%;

Based on our benchmarking against industry peers, the selected target year of 2030, the GHG emissions reduction target metric and the related policies are broadly aligned with prevailing peer practices and international standards. Upon the [REDACTED], we will continue to review our environmental targets and explore the feasibility of setting more ambitious targets to further strengthen our climate resilience.

The table below sets forth key environmental metrics of our business operations^{1,2}:

		For the year ended December 31,		For the six months ended June 30,
	Unit	2024	2025	2026
Emissions				
GHG emissions^{3,4}				
Total (Scopes 2, 3)	tCO ₂ e	858.08	591.61	357.53
(i) Energy Indirect Emissions (Scope 2) . . .	tCO ₂ e	735.54	509.57	284.36
(ii) Other Indirect Emissions (Scope 3) ⁵	tCO ₂ e	122.54	82.04	73.17
Total (Scopes 2) Intensity	tCO ₂ e/GFA	0.12	0.08	0.05
Total (Scopes 2, 3) Intensity . .	tCO ₂ e/ GFA (m ²)	0.14	0.10	0.06
Use of Resources				
Energy				
Total	MWh	3,164.30	2,150.70	1,135.64
(i) Purchased Electricity . .	MWh	831.85	587.63	338.73
(ii) Purchased Steam	MWh	1,206.11	945.28	547.55
(iii) Purchased Cooling	MWh	1,126.35	617.79	249.36
Intensity	MWh/ GFA (m ²)	0.51	0.35	0.18
Exhaust Gas⁶				
HCl	kg	2.64	7.20	1.16
NMHCs	kg	4.08	5.76	5.64
Water				
Total	m ³	6,260.00	4,566.00	2,684.46
Intensity	m ³ / GFA (m ²)	1.01	0.74	0.43

BUSINESS

		For the year ended December 31,		For the six months ended June 30,
	Unit	2024	2025	2026
Waste				
Total Hazardous Waste	tonnes	2.55	3.36	2.60
(i) Laboratory Waste	tonnes	2.45	3.02	2.48
Liquids				
(ii) Waste Chemical	tonnes	–	0.02	0.01
Packaging				
(iii) Waste Packaging	tonnes	0.10	0.03	–
(iv) Waste Activated Carbon	tonnes	–	0.05	0.05
(v) Spent Filter Cartridges	tonnes	–	0.21	–
(vi) Waste Glass	tonnes	–	0.03	0.06
Total Hazardous Waste	tonnes/GFA (m ²)	0.0004	0.0005	0.0004
Intensity				
Total Non-hazardous Waste	tonnes	0.96	0.96	0.26
Total Non-hazardous Waste	tonnes/GFA (m ²)	0.0002	0.0002	0.00004
Intensity				

¹ The data covers the Group’s major business operations.

² Totals may not be the exact sum of numbers stated here due to rounding.

³ The calculation of GHG emissions made reference to the GHG Protocol published by the World Business Council for Sustainable Development (WBCSD) and the World Resources Institute (WRI). Scope 2 (Energy Indirect) emissions cover GHG emissions of indirect energy resulted from purchased electricity, steam and cooling consumed by our operations, while Scope 3 (Other Indirect) emissions that occur in the Group’s value chain.

⁴ The Group’s major business operations did not involve fuel consumption during the Track Record Period, such that we did not generate Scope 1 GHG emissions.

⁵ The Scope 3 emissions include available data arising from Category 6: business travel and Category 7: employee commuting.

⁶ Exhaust gas emissions are derived by based on the average measured emission rate (kg/hour) multiplied by the corresponding operating hours during the Track Record Period.

Social

We are committed to fostering a caring workplace culture that upholds diversity, equal opportunities, health and safety and employee well-being. Our social policy has outlined socially responsible practices and measures.

Employment and Labor Practice

We have established policies governing employment and labor practices, including compensation and dismissal, recruitment and promotion, working hours, rest periods, equal opportunity, diversity, anti-discrimination, and other benefits and welfare. In respect of dismissal, we have established relevant policies to safeguard employees’ lawful rights and interests in employment termination. In terms of diversity and employee benefits, we provide parental leave and childbirth-related benefits to support female employee retention, and offer a range of employee welfare, including paid leave, social insurance and provident fund, as well as festival allowances. We uphold principles of equal opportunity, diversity, and inclusiveness in all aspects of employment and are committed to building an inclusive workplace where all employees are respected and valued, regardless of gender, age, family status, disability, race, religion, nationality or cultural background. In line with our equal opportunity commitment, we uphold age-inclusive practices in recruitment and promotion while supporting extended careers for experienced professionals. We respect labor rights, and strictly prohibit child labor and forced labor.

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We are committed to investing in our workforce. We provide internal and external training to enhance employees’ professional knowledge and skills, and encourage them to pursue further training in their spare time for personal and professional development. We also strive to strengthen employee engagement by regularly arranging leisure activities and maintaining two-way communications to increase overall job satisfaction.

Occupational Health and Safety

We safeguard employees’ health and safety across our operations through implemented policies and measures, including health examinations, provision of personal protective equipment (such as protective eyewear and face shields), regular safety equipment inspections, and safety training covering safe handling of hazardous chemicals. We have also established emergency response measures and plans specifying procedures and departments responsible for handling emergencies. Additionally, we have developed a system of recording and handling accidents, which requires employees to notify their department heads and ensures accidents are managed in accordance with applicable laws and regulations.

Supply Chain Management

We have established a supplier code of conduct which outlines our sustainability expectations including employment practices, health and safety, business ethics, data privacy, product responsibility as well as animal welfare, to guide the selection and management of suppliers, including CROs and CDMOs. Our new supplier selection and regular supplier evaluation criteria include ESG considerations. We also assess supplier qualifications as part of our onboarding and ongoing management processes, and conduct annual evaluations to assess our suppliers’ performance. Where any non-compliance or deficiencies are identified, we require the relevant suppliers to implement rectification measures.

To advance our efforts on providing environmentally preferable products and services, we have established relevant green procurement policies and implemented measures including but not limited to prioritizing products with higher energy efficiency, as well as encouraging our suppliers to adopt environmentally friendly products and services.

Product Responsibility

We are committed to delivering high-quality and safe products and services to our customers. As such, we have established comprehensive quality control and assurance procedures that adhere to applicable national regulatory standards, supported by our quality assurance team. Moreover, we have established measures throughout our operations, from selection of qualified suppliers, incoming material quality control, product in-process quality control to the delivery of finished products, to ensure the quality of our products and services. These measures include but not limited to specifying our quality-related requirements in supplier agreements, conducting regular on-site inspections, ensuring that clinical trial personnel possess valid Good Clinical Practice (“GCP”) certification, establishing quality control procedures, as well as product and raw material quality inspection guidelines. Additionally, we have established dedicated recall and destruction procedures for non-conforming or scrapped clinical trial drugs, with such materials and experimental medications handled in accordance with the relevant policies.

To ensure customer satisfaction, we have put in place procedures for handling customer complaints. To safeguard customer privacy, we have also established preventive and protection measures, including user access restrictions to customer information. Our Ethics Task force conducts professional ethical reviews and oversight to ensure the strict confidentiality of clinical trial participants’ personal data. We have established policies governing advertising and marketing activities, with materials subject to review before publication to prevent false or misleading information.

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Patient Safety

Patient safety is our top priority. To further enhance the safety of patients enrolled in our clinical development activities, we have adopted a range of measures including: (i) preparing and updating clinical trial protocols, informed consent forms and Investigator’s Brochures (“IBs”) in accordance with applicable regulations and relevant safety information; (ii) providing relevant training to personnel; (iii) procuring clinical trial insurance to cover trial-related injuries; (iv) establishing procedures for the reporting and management of adverse events, including timely reporting of serious adverse events and implementation of necessary medical measures; and (v) conducting ongoing monitoring and quality checks to ensure compliance with protocols and protection of patient safety.

Animal Welfare

We are committed to the ethical use of laboratory animals and apply the principles of replacement, reduction and refinement (“3Rs”), which aim to replace the use of animals where possible, reduce the number of animals used and refine procedures to minimise pain or distress. As we engage qualified CROs to conduct animal studies, we require such CROs to hold relevant qualifications and accreditations, including AAALAC certification, which is designed to promote the humane treatment of animals in science, and a Certificate for Use of Experimental Animals. We require our CROs to complete an animal welfare and ethics application form to ensure animal welfare is duly protected. Animal studies are subject to ethical review procedures, including assessment of the necessity of animal use, application of the 3Rs principles, appropriate selection of animal models and guidelines on humane endpoints. We also leverage our AI-enabled core R&D platform to support animal welfare by enabling early-stage in silico screening and targeted candidate selection prior to animal studies, thereby reducing the number of candidates requiring in vivo testing where practicable. In addition, we provide regular training to our employees on animal welfare and ethical research practices.

Business Ethics

We uphold high standards of business ethics, and strictly prohibit bribery, extortion, fraud, money laundering and any other unethical practices. We have established preventive measures, including anti-corruption training for the Board and employees, and whistleblowing channels for employees to report any potential misconduct that violates our ethical standards. The Board is responsible for the oversight of these preventive measures and whistleblowing procedures.

Community Investment

We strive to contribute to the community and shoulder corporate responsibility. During the Track Record Period, we partnered with universities in support of youth development. Moving forward, we will explore opportunities to establish additional focus areas for community investment, and partnerships with social impact organizations where appropriate.

Social Metrics and Targets

To strengthen our commitment to safeguarding employee health and safety, we have established targets to maintain (i) zero major safety incidents and (ii) zero work-related fatalities for our employees at our operational sites.

Upon benchmarking against industry peers, our occupational health and safety target metrics, as well as our policies, are aligned with prevailing practices among peers. Upon the [REDACTED], we will progressively review our social targets and continue to explore the feasibility of setting more ambitious targets to further advance our workplace health and safety efforts.

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The table below sets forth key social metrics of of the Group, all of whose employees were full-time employees.

Workforce⁶

		For the year ended December 31,		For the six months ended June 30,
	Unit	2024	2025	2026
<i>By gender</i>				
Male	Number	36	32	35
Female	Number	41	33	29
<i>By age group</i>				
At or below 30	Number	25	18	17
Between 31-50	Number	46	43	42
At or above 51	Number	6	4	5
<i>By geographical location</i>				
PRC	Number	72	62	61
the United States	Number	5	3	2
Hong Kong	Number	0	0	1

⁶ The decrease in the total number of employees was mainly due to voluntary resignations and business restructuring to enhance operational efficiency. The Group considers that such decrease did not have any material adverse impact on its business operations.

Occupational Health and Safety

The Group did not experience any major work safety-related incidents involving our employees during the Track Record Period and up to the Latest Practicable Date.

INSURANCE

We maintain insurance policies for adverse events in clinical trials, liabilities of directors, supervisors and senior management, and fixed assets. We currently do not maintain product liability insurance. For more details, see “Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

CERTIFICATES, PERMITS AND LICENSES

As of the Latest Practicable Date, our PRC Legal Adviser and U.S. Legal Adviser confirmed that we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations in the PRC and the United States, and such licenses, permits and certifications all remained in full effect. For more details regarding the laws and regulations to which we are subject, see “Regulatory Overview.” We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. To the best knowledge of our PRC Legal Adviser and U.S. Legal Adviser, there is no material legal impediment in renewing such licenses, permits, approvals and certificates as

BUSINESS

they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

<u>Licnese/Permit</u>	<u>Issuing Authority</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Zhejiang Province Pathogenic Microorganism Laboratory Filing Certificate	Hangzhou Municipal Health Commission	August 12, 2024	N/A
Zhejiang Province Pathogenic Microorganism Laboratory Filing Certificate	Hangzhou Municipal Health Commission	February 27, 2024	N/A
Fixed Pollution Source Discharge Registration Receipt	N/A	November 4, 2024	November 3, 2029

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

On March 27, 2026, Shanghai Jiayin Biotechnology Co., Ltd.(上海嘉因生物科技有限公司) (the “**Shanghai Jiayin**”) filed a lawsuit with the Intermediate People’s Court of Suzhou Municipality, Jiangsu Province (the “**Suzhou Court**”), alleging that the inclusion of the words “嘉因” and “嘉因生物” in the enterprise name of Hangzhou Jiayin constitutes trademark infringement and unfair competition, and seeking damages of RMB60.0 million. We received a summons dated June 30, 2026 issued by the Suzhou Court, requiring us to attend a hearing on August 13, 2026, which was cancelled subsequently. On July 13, 2026, we submitted an objection to jurisdiction to the Suzhou Court, requesting that the case be transferred to the Intermediate People’s Court of Hangzhou Municipality for trial. As of the Latest Practicable Date, we had not received any response from the Suzhou Court regarding our objection to jurisdiction, and the case had not commenced trial.

Our PRC legal adviser with respect to intellectual property laws in the PRC is of the view that the infringement claims asserted by Shanghai Jiayin are without merit, and that the risk of our being required to pay RMB60.0 million in damages in connection with such alleged infringement is remote.

Saved as disclosed above, during the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings. We are committed to maintaining the standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

Legal Compliance

Our PRC Legal Adviser and U.S. Legal Adviser confirmed that, based on the due diligence conducted by our U.S. Legal Adviser in connection with the [REDACTED], during the Track Record Period and up to the Latest Practicable Date, we have complied with all applicable laws and regulations in PRC and the United States in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

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Labor and Social Security Non-compliances

As of the Latest Practicable Date, we have identified the following historical non-compliance incidents in respect of our labor and employment, social insurance, and housing provident fund matters in China.

Failure to Make Full Social Insurance and Housing Provident Fund Contributions and Historical Use of Third-Party Payment Agencies

Background and Reasons

During the Track Record Period and up to the Latest Practicable Date, we did not pay social insurance and housing provident fund in full for certain employees based on their actual wages in accordance with the applicable PRC laws and regulations. The shortfall of social insurance and housing provident fund contributions amounted to an aggregate of approximately RMB0.8 million during the Track Record Period. This non-compliance incident was primarily caused by delays by our human resources department in updating the applicable bases of the social insurance and housing provident fund contributions after salary adjustments of some employees.

Additionally, during the Track Record Period, certain of our PRC subsidiaries historically engaged third-party agencies to make social insurance and housing provident fund contributions on behalf of a small number of their employees, which is not in compliance with relevant PRC regulations requiring employers to handle such payments directly.

Legal Consequences and Potential Maximum Penalties

Our PRC Legal Advisors have advised that our historical practices were not in full compliance with the relevant PRC laws and regulations. Specifically, pursuant to Article 58 of the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), an employer must apply to register its employees for social insurance within 30 days of their employment. Furthermore, Article 60 of the Social Insurance Law stipulates that an employer must itself declare and pay social insurance contributions in full and on time. Consequently, the practice of engaging third-party agencies to make contributions on behalf of employees is inconsistent with this legal requirement for the employer to handle such matters directly. Failure to comply with these obligations can lead to penalties. Under Article 84 of the Social Insurance Law, where an employer fails to complete social insurance registration, the social insurance administrative department shall order it to rectify the situation within a prescribed time limit; if the employer fails to do so, it may be subject to a fine of one to three times the amount of the social insurance fees owed, and its directly responsible managers and other directly responsible personnel may be subject to a fine of between RMB500 and RMB3,000.

Our PRC Legal Advisors have advised that the use of third-party agencies could be deemed by the relevant authorities as a failure to properly handle social insurance registration, which may potentially give rise to the imposition of penalties. Separately, pursuant to Article 86 of the Social Insurance Law, where an employer fails to pay social insurance contributions in full and on time, the social insurance collection agency shall order it to make supplementary payments within a prescribed time limit and may be subject to a daily late fee of 0.05% of the overdue amount, commencing from the date of default. If the employer fails to pay within the prescribed time limit, the relevant administrative department may impose a fine of one to three times the amount of the overdue payment. In relation to the housing provident fund, pursuant to the Regulations on the Management of Housing Provident Fund (《住房公積金管理條例》), where an employer fails to pay or underpays housing provident fund contributions, the housing provident fund management center shall order it to make the payment within a prescribed time limit. If the employer fails to do so upon the expiry of the time limit, the center may apply to a people's court for compulsory enforcement.

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Remedies and Mitigating Factors

As of the Latest Practicable Date, we have ceased the practice of using third-party agencies for contribution payments. We had not received any notice from any competent authority requiring us to make supplementary payments or rectify the shortfalls, nor had we been subject to any investigations or administrative penalties in relation to such non-compliance. We had also not received any complaints or reports from our employees regarding these matters. We have made full social insurance contributions for all our employees.

Based on public credit reports and relevant compliance certificates obtained from governmental authorities, there was no record of us having been subject to administrative penalties for violations of social insurance or housing provident fund laws and regulations during the Track Record Period. In addition, we have enhanced our internal control measures in this regard, in particular, (i) we have implemented comprehensive policies on social insurance and housing provident fund contribution and registration in compliance with the relevant PRC laws and regulations; (ii) we have designated our human resources department to review and monitor the reporting and contributions on a regular basis; (iii) we provide regular training to our employees regarding compliance requirements and relevant laws and regulations; and (iv) we actively communicate with our employees to seek their understanding and cooperation in complying with the applicable contribution base, which also requires additional contributions from the relevant employees. If relevant authorities request rectification within a specified period, or if there are any reports, disputes, complaints, or requirements to pay overdue social insurance fees and late payment penalties or supplementary housing provident fund contributions, we will promptly rectify, resolve the reports, disputes or complaints, or make full supplementary payments within the prescribed time limit.

PRC Legal Advisors’ Opinion

Based on the foregoing, and on the condition that there are no material changes to the current laws and local enforcement policies and we do not receive any related employee complaints or reports, our PRC Legal Advisors are of the view that the risk of our Group being subject to administrative penalties as a result of the historical failure to make full contributions and the use of third-party agencies is remote.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in general market conditions and the regulatory environment of China, the U.S. and other target markets, our ability to develop, manufacture and commercialize our product candidates, and our ability to compete with other pharmaceutical companies. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit, liquidity and currency risks that arise in the normal course of our business.

We have established an audit committee and also adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. The following key principles outline our approach to risk management:

- Our board of directors will oversee and manage the overall risks associated with our business operation, including (i) reviewing and approving our risk management policies to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iv) reviewing our corporate risk in light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Company.

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- Our operation department is responsible for (i) formulating and updating our risk management policy and targets; (ii) reviewing and approving major risk management issues of our Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments’ reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Company; and (viii) reporting to our board of directors on our material risks.
- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to standardize risk management across our Company and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board of Directors is responsible for establishing and ensuring effective internal controls to safeguard our Shareholder’s investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have established anti-bribery and anti-corruption measures, which set forth procedures for identifying potential frauds and corruption, implementing relevant anti-corruption procedures and setting out anti-corruption responsibilities for relevant personnel. We strictly prohibit bribery or other improper payments in any of our business operations. This prohibition applies to all business activities, whether involving government officials, influential personnel or private or public payors. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. We provide employees with adequate communication channels. If employees have any questions about anticorruption compliance principles, they should promptly contact their supervisor or company compliance team. We encourage employees to take the initiative to seek guidance from us regarding anti-corruption policy principles. We have also put in place whistleblower mechanism so that employees can timely report relevant incidents in time to compliance team according to our anti-corruption measures.

We plan to maintain strict anti-corruption policies among our employees in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We have not had any corruption incidents in our history.

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- We have established procedures to protect the confidentiality of patients’ personal data. We maintain policies which require our personnel to be trained on collecting, and safeguarding personal information. We also require our CROs to have data protection clauses in our agreements with them under which they are responsible for safeguarding data in their possession. Access to clinical trial data has been strictly limited to authorized personnel only according to the good clinical practice and relevant regulations. Additionally, we require external parties and internal employees involved in clinical trials to comply with applicable confidentiality requirements. Data can only be used for the intended purpose, as agreed by the patients and the data usage shall be consistent with the informed consent form. We have a number of ongoing or planned clinical studies. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable data and privacy protection laws.
- We have adopted various measures and procedures regarding each aspect of our business operation, such as protection of intellectual property, environmental protection, and occupational health and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program.
- Our Directors (who are responsible for monitoring the corporate governance of our Company), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee, which (i) makes recommendations to our Directors on the appointment and removal of external auditors; (ii) reviews the financial information and renders advice in respect of financial reporting; and (iii) oversee internal control procedures of our Company.
- We have engaged Mango Financial Limited as our compliance advisor to provide advice to our Directors and management team. Our Compliance Advisor is expected to, upon our consultation, provide advice and guidance in respect of compliance with the applicable laws and Listing Rules including various requirements of directors’ duties and internal control in a timely fashion.
- We plan to engage a PRC law firm to advise us on and keep us abreast of PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings sessions to be provided by external legal advisors from time to time when necessary, and/or any appropriate accredited institution to update our Directors, senior management and relevant employees on the latest PRC laws and regulations.
- We will comply with the Corporate Governance Code, except for the deviation from the code provision A.2.1 of the Corporate Governance Code. We have set out respective terms of reference of directors and senior management in compliance with the Corporate Governance Code. For further details, see the section headed “Directors and Senior Management.”
- Our Directors believe that compliance creates value for us and dedicate to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behaviour across the organization, we regularly conduct internal compliance checks, inspections and compliance training.

During the Track Record Period, we have regularly reviewed and enhanced our internal control system.