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OVERVIEW

We are a clinical-stage gene therapy company, dedicated to delivering safe, effective and affordable gene therapy treatments to patients worldwide. Our mission is to advance gene therapies that address significant unmet medical needs, particularly large-market or currently untreatable diseases, to provide durable clinical benefits from a single administration. Our pipeline includes multiple valuable assets supported by clinical data that enable advancement into pivotal studies, particularly in ophthalmic diseases. We are also expanding into cardiovascular and neurological indications. Our engineered capsid and optimized payload design, supported by our advanced manufacturing process, help reduce immunogenicity and offer the potential for a better safety profile and durable therapeutic effect. To our knowledge, we are among the few gene therapy-focused biotech companies globally, and the first in China, to establish commercial-scale Baculovirus/Spodoptera frugiperda Sf9 insect cell (“**Bac/Sf9**”)-based rAAV manufacturing, which provides a meaningful cost advantage for future commercialization.

Gene therapy has the potential to change the way patients are treated by correcting the underlying genetic defect that is the cause of their disease or blocking the pathogenic mechanism. Gene therapy as a treatment method is relatively new but well validated, with more than a dozen gene therapy products approved by regulators globally. The gene therapy industry is shifting from rare diseases to more prevalent, large-market indications. Meanwhile, ophthalmic diseases — owing to the localized delivery options, immune-privileged environment, and unmet-medical needs — have emerged as a promising area. Large-market ophthalmic diseases such as neovascular age-related macular degeneration (“**nAMD**”) and diabetic macular edema (“**DME**”) offer great potential for gene therapy.

Since our inception in 2019, we have been dedicated to the in-house development of recombinant adeno-associated virus (“**rAAV**”) gene therapies. We have developed a differentiated and clinically advanced pipeline. Our Core Products, which are in advanced stages of clinical development for treating XLRP, nAMD and DME, have demonstrated clear advantages in efficacy and/or safety in clinical studies, with great potential to address global unmet medical needs at an affordable price.

We are one of the few gene therapy companies worldwide with an end-to-end integrated operational system, combining scientific insights with executional excellence to achieve efficient pipeline progression. Our Boston center is responsible for drug discovery and early-stage research, our Shanghai center leads Investigational New Drug (“**IND**”)-enabling studies and clinical trials, and our Suzhou center meets our manufacturing needs. Our multi-disciplinary team integrates deep expertise across scientific, translational, clinical, and manufacturing disciplines in gene therapy. This expertise enables precise indication selection, well-designed clinical study plans, and efficient participant recruitment. We believe that the greater efficiency of clinical development and cost-effectiveness of manufacturing in China will constitute key competitive advantages for us in the development and potential commercialization of our therapies globally.

We built our rAAV gene therapy R&D platform, EXACTE™, to enable the selection of drug candidates with better tissue tropism, high transduction efficiency, long-term effectiveness and a strong safety profile. EXACTE™ focuses on three key aspects of gene therapy R&D: capsid engineering, payload engineering, and target tissue screening. We engineer capsid variants to have better transduction and tissue tropism and optimize baculovirus rep/cap vector design to improve rAAV production quality and capsid potency. Our payload engineering optimizes the genetic payload for each drug candidate to achieve higher and more sustained therapeutic protein levels, improved safety, and reduced risk of immune-related side effects. Our target tissue screening integrates comprehensive *in vitro* and *in vivo* screening systems to evaluate the efficacy, safety, and toxicity of candidate constructs at the preclinical stage.

We are the only gene therapy biotech company in China to establish commercial scale Bac/Sf9-based rAAV manufacturing. Our AAVANCE™ manufacturing platform enables cost-efficient, scalable production of our gene therapy products with low empty capsid rate and high product quality. We have attained exceptionally low empty capsid rates below 1%, significantly better than the industry norm of close to 30%. Low empty capsid rates are a key milestone because empty capsids negatively impact both safety and effectiveness, increasing the overall viral load without contributing to clinical efficiency. These capabilities allow us to deliver revolutionary and affordable rAAV gene therapy solutions with high potency, efficiency, and safety — three key factors for the success of gene therapy products.

Our Pipeline

Our pipeline currently includes two Core Products and one Key Product as well as three other preclinical and early-stage gene therapies for the treatment of ophthalmic and cardiovascular diseases. We have developed all of these therapies in-house and we hold the global intellectual property rights to all of them.

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The following chart shows the pipeline of gene therapies we have under development:

Therapeutic area	Product	Target	Route of administration	Indication	Pre-clinical	Clinical stage			Regulatory designation	Regulatory authorities	Latest milestone	Near-term milestones	Commercial rights	Intended commercialization jurisdictions ²
						Phase 1	Phase 2	Phase 3						
Ophthalmic Diseases	★ FT-002	RPGR	Subretinal	XLRP	Ph 2 completed				FDA Orphan Drug Designation and Fast Track Designation	NMPA, FDA	China Ph 2 completed in Aug-26	Commence China Ph 3 by 2Q2027	Global	China; Ex-China (develop in-house or through partnership)
				nAMD	Ph 2 completed				FDA RMAT Designation		China Ph 2 completed in Jul-26 Ph 2 IND approved by FDA in Nov-24	Commence China Ph 3 by 1Q2027		
	★ FT-003	VEGF	Intravitreal	DME	Ph 2 enrollment completed					NMPA, FDA	China Ph 2 enrollment completed in Jan-26 Ph 2 IND approved by FDA in Dec-24	Commence China Ph 3 by 3Q2027	Global	China; Ex-China (develop in-house or through partnership)
				DR	Ph 2 IND approved						Ph 2 IND approved by NMPA in Mar-25			
	◆ FT-001	RPE65	Subretinal	RPE65-related IRDs	Ph 2 completed; Ph 3 IND approved				CDE Breakthrough Therapy Designation	NMPA, FDA	China Ph 2 completed in Feb-25; Ph 3 IND approved by CDE in Sep-25		Global	China; Ex-China (develop in-house or through partnership)
Cardiovascular Diseases	FT-023	Undisclosed	Intravitreal	nAMD/DME/DR						N/A			Global	Global
	FT-017	MYBPC3	Intravenous	HCM	Ph 1/2 IND approved					NMPA, FDA	IND approval obtained from both NMPA and FDA in Apr-25	Commence China Ph 1 by 4Q2027	Global	China; Ex-China (develop in-house or through partnership)
	FT-018	PKP2	Intravenous	ARVC						N/A			Global	Global

★ Core products ◆ Key product

China progress

US progress

Notes:

- * Competent authorities in respective jurisdictions: National Medical Products Administration (NMPA) for China, the Food and Drug Administration (FDA) for the U.S.
 1. Obtained IND approval from the FDA for Phase II clinical trials based on CMC, preclinical, and Phase I clinical data generated in China.
 2. We hold global rights for all of our product candidates. For FT-002, FT-001, FT-003, FT-001, FT-001, we plan to conduct development by ourselves in China for future commercialization. For overseas market, we will consider developing by ourselves (exact timeline to be confirmed subject to our resources allocation and management's judgment of the latest regulatory and market conditions and the competitive landscape) or seeking local partners for development and commercialization. Preclinical assets are not yet assigned specific jurisdictions given their early development stage.

Abbreviations: RPGR = retinitis pigmentosa GTPase regulator; VEGF = vascular endothelial growth factor; RPE65 = retinal pigment epithelium-specific 65 kDa protein; MYBPC3 = myosin-binding protein C3; PKP2 = the gene encoding Plakophilin-2; XLRP = X-linked retinitis pigmentosa; nAMD = neovascular age-related macular degeneration; DME = diabetic macular edema; DR = diabetic retinopathy; IRD = inherited retinal dystrophy, including leber congenital amaurosis type 2 (LCA2), retinitis pigmentosa (RP), etc; HCM = hypertrophic cardiomyopathy; ARVC = arrhythmogenic right ventricular cardiomyopathy; Ph = Phase; CDE = Centre for Drug Evaluation

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STRENGTHS

We believe the following strengths provide us with a distinct competitive advantage and differentiate us from other gene therapy companies.

Differentiated gene therapy pipeline with leading positions in clinical advancement in China

Leveraging our EXACTE™ and AAVANCE™ technology platforms, we have built a differentiated and competitive pipeline with leading positions in terms of clinical advancement in China. With robust clinical data validating our technology platforms, we have expanded our pipeline further to cardiovascular and neurological indications. We have multiple pipeline assets that have demonstrated strong competitive advantages, and we hold full global rights to all of our drug candidates.

We have two Core Products and one Key Product:

- Our Core Product FT-002 is a drug candidate for the treatment of X-linked retinitis pigmentosa (“**XLRP**”). XLRP is one of the most common and severe forms of inherited retinal diseases (“**IRD**”), typically presenting before the age of 10 and progressing to legal blindness before the age of 50. Currently there are no approved treatments for XLRP globally. FT-002 was granted Orphan Drug Designation by the FDA in January 2024 and Fast Track Designation in October 2024. We have completed Phase II clinical trials of FT-002 in China and have received clearance from the FDA for Phase II trials in the United States. In clinical studies, FT-002 has demonstrated strong preliminary efficacy and a favorable safety profile thus far. Up to the longest follow-up of three years, FT-002 was safe and well tolerated. Most treatment-emergent adverse events (“**TEAE**”) were related to the surgical procedure or protocol-required steroids and were effectively managed with standard care. Importantly, FT-002 showed certain sustained improvements in visual acuity, retinal function and structure, as well as the quality of life related to vision.
- Our Core Product FT-003 is an intravitreal drug candidate for the treatment of nAMD and DME. nAMD is characterized by choroidal neovascularization, in which abnormal blood vessels form in the retina. DME is a serious complication of diabetes mellitus where high blood sugar damages the retinal blood vessels, causing fluid or blood leakage beyond the retina’s capacity to absorb it. Both can lead to blindness. In 2025, there were 4.2 million nAMD patients and 7.8 million DME patients in China, and 1.6 million nAMD patients and 2.0 million DME patients in the United States. Current treatments for nAMD and DME involve frequent intravitreal injections of anti-VEGF antibodies, which are burdensome, unpleasant, and over time expensive. Multiple injections also entail a higher risk of side effects and complications. The result is low patient compliance with poor long-term outcomes. FT-003 has the potential to reduce the treatment burden to a single shot administered in an outpatient clinic. We have completed Phase II clinical trials of FT-003 for nAMD in China, initiated Phase II clinical trials of FT-003 for DME in China, and obtained FDA clearance for Phase II trials in the United States for both nAMD and DME. FT-003 with respect to nAMD was granted regenerative medicine advanced therapy (RMAT) designation by the FDA in July 2026. FT-003 has demonstrated significant therapeutic benefits in clinical trials of nAMD and DME thus far, and a favorable safety profile across all tested dose levels. Participants treated with FT-003 showed significant improvements in visual acuity and retinal structure, and no additional anti-VEGF treatments were required in treatment-naïve participants monitored for up to three years.
- Our Key Product FT-001 is a drug candidate for treating IRD caused by biallelic mutations in the RPE65 gene. It is our drug candidate at the most advanced stage of clinical development, and its robust clinical results provided early validation for our technology platforms. RPE65-related IRD is characterized by a progressive and irreversible decline in vision that results in blindness. Conventional management may slow but cannot halt disease progression, while

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the only approved gene therapy treatment is expensive and has not been approved in China. FT-001 obtained Breakthrough Therapy designation from the CDE of the NMPA on June 26, 2025, and we have completed Phase I/II clinical trials of FT-001 in China. Our Phase III clinical trial plan has been approved by the CDE of the NMPA in September 2025. FT-001 is generally safe and well tolerated with no dose-limiting toxicity (“**DLT**”), and most ocular events were mild in severity. FT-001 greatly improved functional vision and retinal sensitivity as early as Week 4 and has demonstrated continued effectiveness through almost two years of post-trial observations thus far.

Our pipeline also includes one other gene therapy drug candidates in ophthalmic diseases and two in cardiovascular diseases. Aside from FT-017, all of these drug candidates are still in the preclinical stage. These other drug candidates include the following:

- FT-023 is a gene therapy drug candidate in the preclinical stage of study for treating nAMD, DME and diabetic retinopathy (“**DR**”). FT-023 can be an effective therapy for retinal vascular leakage disorders other than the anti-VEGF therapy, as it focuses on a biological target. When combined with the anti-VEGF pathway, FT-023 can have elevated efficacy on nAMD and DME patients and potentially treat the patients who do not respond well to anti-VEGF treatments.
- FT-017 is a gene therapy drug candidate for treating MYBPC3 mutation-associated hypertrophic cardiomyopathy (“**HCM**”). FT-017 is the first rAAV gene therapy for HCM caused by MYBPC3 gene mutations to enter clinical trials in China.
- FT-018 is a gene therapy drug candidate in the preclinical stage of study for treating arrhythmogenic right ventricular cardiomyopathy (“**ARVC**”) caused by mutations of the PKP2 gene. FT-018 is the only rAAV gene therapy for ARVC caused by PKP2 gene mutations that has been disclosed in China.

AAVANCE™, our Bac/Sf9 manufacturing platform enabling safe, scalable and cost-efficient manufacturing with high product quality

Two of the greatest challenges in the gene therapy industry are safety and cost. We believe that our AAVANCE™ manufacturing platform will enable us to overcome both of these challenges. We have established one of the only GMP-compliant, Bac/Sf9 cell-based viral culture gene therapy production infrastructures in China. As shown in the table below, Bac/Sf9-based production has significant advantages in manufacturing cost, batch-to-batch consistency, empty capsid rates, scalability and yield compared with HEK293, the other commonly used production method. We are able to achieve empty capsids rate of less than 1%, significantly enhancing product safety by minimizing process-related impurities. Empty capsids are considered critical impurities in rAAV gene therapy, as their presence increases the total capsid dosing and potentially elevates the risk of immune response. We have already implemented product processes for six programs that satisfy U.S. and Chinese requirements for clinical-trial product quality.

Category	Bac/Sf9	HEK293	Descriptions
Manufacturing Cost . .	Relatively low	Relatively high	The cost of rAAV manufacturing in Bac/Sf9 is generally lower, driven by inexpensive media and efficient infection-based production. HEK293 production is more expensive due to the need for large quantities of high-quality plasmids, costly transfection reagents, and more demanding mammalian cell culture processes.

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Category	Bac/Sf9	HEK293	Descriptions
Batch-to-Batch Consistency	High	Moderate	Batch-to-batch consistency is a key advantage of the Bac/Sf9 platform. Once the baculovirus master bank is established, production under consistent multiplicity of infection conditions results in minimal variability between batches. In contrast, the HEK293 system, relying on transient transfection, exhibits greater batch-to-batch variation due to inherent differences in transfection efficiency and plasmid quality in each production run.
Empty Capsid Rates	Relatively low	Relatively high	The Bac/Sf9 system generally results in lower empty capsid rates. rAAV from the HEK293 platform had a full/empty capsid ratio of 70.8%, while rAAV from the Bac/Sf9 system had a full/empty capsid ratio of 93.2%, demonstrating a markedly lower empty capsid rate for the Bac/Sf9 system. ⁽¹⁾
Scalability	High (100–2000+ L)	Moderate; limited by transfection	The Bac/Sf9 system is highly scalable, with insect cells readily expanding in large stirred-tank bioreactors reaching 2,000 liter volumes, making it well suited for large-scale GMP manufacturing. In comparison, the scaling of the HEK293 system is limited by the efficiency and cost of plasmid transfection.
Yield	High and scalable	Moderate	The Bac/Sf9 system typically achieves high volumetric yields, benefiting from efficient infection and good scalability. HEK293 yields are moderate and more sensitive to transfection efficiency and plasmid quality. In the same head-to-head study discussed above, rAAV from Bac/Sf9 cells had approximately 40-fold higher yields than rAAV from HEK293 cells. ⁽¹⁾ In addition, publicly available studies have reported that Bac/Sf9 systems may achieve productivity levels of approximately 7×10^4 purified rAAV particles per cell under optimized experimental conditions.
Infectivity	Relatively high	Relatively low	The Bac/Sf9 system typically achieves higher infectivity. rAAV from Bac/Sf9 system had a higher tissue culture infectious dose/viral genome than rAAV from HEK293 platform, indicating better infectivity. ⁽¹⁾

Note:

- (1) Systematic comparison of rAAV vectors manufactured using large-scale suspension cultures of Bac/Sf9 system and HEK293 platform originates from a head-to-head study in which AAV2.N54-aflibercept vectors were produced under matched upstream/downstream protocols in Bac/Sf9 system and HEK293 platform, at both 2 liters and 50 liters, followed by identical analytics for yield, capsid content and infectivity.

Source: Literature Review (systematic comparison of rAAV vectors manufactured using large-scale suspension cultures of Sf9 and HEK293 cells), Frost & Sullivan Report

Our AAVANCE™ manufacturing platform enables high-quality gene therapy production at scale, with exceptional efficiency and cost advantages. AAVANCE™ boasts an industry-leading GMP-compliant production capacity of 500L. Currently, laboratory-scale rAAV production typically achieves yields in the range of 10^{12} – 10^{14} vector genome (“vg”) per litre; in comparison, our bioreactors achieve upstream production yields of more than 10^{15} vg/L, which places us among the industry leaders in this respect, according to Frost & Sullivan. Our high-yield, high-purity production also facilitates process stability and enables

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us to reach downstream purification yields of 50%. We have sufficient capacity to support clinical development and initial commercialization, and Bac/Sf9-based production is more accessible and requires lower media and infrastructure costs to grow as compared to other commonly used methods, which facilitates further expansion when and as needed. Our rAAV drug products are manufactured using an advanced aseptic preparation isolator filling system, and we have also established a robust and fully integrated quality control and assurance system with in-house testing capability, ensuring that we maintain a high level of product consistency and quality. With the above, we are able to accomplish a significantly lowered cost of developing gene therapy drugs, which supports lower pricing and higher accessibility. By our estimate, we are able to achieve a level of total cost per batch of FT-001 that is as much as 90% lower compared to the only gene therapy treatment option approved in the United States and Europe for the target disease of FT-001. Together, these factors enable faster development, lower manufacturing costs, and reduced patient treatment costs, providing a sustainable competitive edge in both clinical and commercial settings.

Strong translational medicine and clinical operation capabilities leveraging strengths in China and the United States

We have full-spectrum translational medicine capabilities bridging fundamental scientific research with clinical development. We have formed a dedicated team of experts in clinical sciences, led by Dr. Xinyan Li, overseeing clinical trial strategy, supporting clinical trials with scientific evidence, and providing medical interpretation of clinical trial results. These capabilities enable swift conversion from scientific discovery to clinical programs.

We capitalize on the strengths of global hubs of biotechnological research in both the United States and China while maintaining a unified global R&D strategy and leveraging the greater efficiency and cost-effectiveness of clinical trials in China. Our Boston center is responsible for drug discovery and early-stage research, including capsid screening and viral vector construction and optimization. Our Shanghai center handles translational medicine and clinical trials, including IND-enabling studies, IND applications and the clinical trials themselves. Our Suzhou center fulfills the manufacturing needs of our non-clinical and clinical trials while preparing for commercial-scale production.

Our clinical operation capabilities progress early-stage innovation and preclinical studies into clinical trials with minimal delays. Leveraging our established relationships with leading hospitals and research institutions, we have been able to achieve efficient site activation and protocol deployment. This infrastructure supports faster participant enrollment and higher data throughput, which are critical for accelerating development timelines. It has taken us as little as 11 months to advance a drug candidate from concept stage to IND approval. Since our inception, we have successfully advanced three drug candidates to Phase II clinical trials.

EXACTE™, our rAAV gene therapy R&D platform supporting product development with global intellectual property protection

Our R&D platform, EXACTE™, is our integrated system to enhance the accuracy, efficiency, and safety profile of therapeutic gene delivery. EXACTE™ is designed to accelerate the development of gene therapies through precision engineering and targeted delivery. Supported by an integrated *in vitro* and *in vivo* screening system, EXACTE™ enables the selection of drug candidates with optimal tissue tropism, high transduction efficiency, durable expression, and a strong safety profile with a competitive cost structure.

EXACTE™ focuses on three key aspects of gene therapy R&D:

- *Capsid engineering:* With our rAAV capsid technology, we are able to refine the tropism of rAAV capsids to accurately target specific tissues and cell types, minimizing off-target effects and improving therapeutic outcomes, as well as improve compatibility with our Bac/Sf9 production system to achieve enhanced vector potency and production quality.
- *Payload engineering:* We employ sophisticated strategies to tailor transgene constructs, including codon sequencing to boost transgene expression and

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- regulatory element refinement including enhancers, promoters, and introns to improve transcription and translation efficiency.
- *Candidate screening:* We have implemented a robust framework to select lead constructs for further development, including specially designed assays to evaluate performance and transgene expressions, *in vitro* and *in vivo* models for efficacy screening, and comprehensive toxicity evaluations for de-risk candidate selection.

Deep expertise in gene therapy across research, translational, clinical, and manufacturing disciplines

Our management team comprises leaders with rich industry experience and strong scientific expertise in cell and gene therapy, including the research, translational, clinical, and manufacturing aspects of operating a clinical stage gene therapy enterprise. We believe that the breadth, depth and diversity of experience within our management team is a core strength of our company.

Dr. Xinyan Li, our chief executive officer and chief medical officer, has over 25 years of expertise in innovative drug development, including cell and gene therapy. In the course of her career, Dr. Li has advanced multiple therapies from preclinical to clinical stages, with a focus on biologics and cell therapy. Her leadership has been pivotal in securing regulatory approvals in both China and the United States. Prior to her move to industry, Dr. Li spent five years practicing internal medicine and a decade teaching and conducting scientific research at medical schools, including conducting research on gene and cell therapy as a visiting scholar at the Faculty of Medicine of the University of Montpellier in France. She has also served as a principal investigator for several national research projects.

Dr. Zhongdong Shi, our senior vice president and head of R&D, brings over a decade of innovation and leadership in cell and gene therapy research and development. Dr. Shi’s work has led to over 10 IND approvals in the US and China, and he has authored over 30 publications and holds more than 10 patents. Dr. Shi was a co-developer of the iCRISPR platform and investigated human developmental diseases using pluripotent stem cells, and he has extensive expertise in developing gene therapy, stem cell therapy, and CAR-T and iPSC-NK therapies.

In addition, we have built a comprehensive, efficient and long-serving internal team, with experience covering all key stages of the R&D cycle. Our head of manufacturing, Peng Yang, has 16 years of experience in biotech, chiefly in process development; he oversees our chemistry, manufacturing and controls (“CMC”) functions, including process development, transfer and scale-up, clinical sample production, registration application and project management. Our senior director of translational medicine, Dr. Chao Ren, has 12 years of experience in biotech since completing her PhD, in a variety of areas including management of preclinical pipeline projects, research, preclinical pharmacology, pharmacokinetics and safety evaluations; she is in charge of our translational medicine operations, including non-clinical efficacy and toxicology, clinical pharmacology, and clinical biosample analysis. Our senior director of clinical operations, Minghui Xue, has 15 years of experience in biotech, specializing in the management of clinical trials; he is in charge of clinical research project management. Our senior director of quality control, Dr. Aiqun Li, has 15 years of experience at leading biotechnology companies and research institutions.

STRATEGIES

Accelerate the clinical development of our mid- to late-stage ophthalmic drug pipeline

We intend to advance FT-002 and FT-003 through clinical development and seek approval for commercialization as expeditiously as possible.

We have completed Phase II clinical trials for FT-002 in China. We anticipate initiating Phase III by the second quarter of 2027. We will also continue pursuing development and approval for FT-002 in the United States, leveraging its Orphan Drug Designation and Fast Track Designation status. The FDA has approved Phase II clinical trials for FT-002 in the United States.

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We are advancing FT-003 for both nAMD and DME indications. We have completed Phase II clinical trials for nAMD in China and anticipate initiating Phase III by the first quarter of 2027. We have also completed Phase II participant recruitment for DME in China and expect to initiate Phase III by the third quarter of 2027. In addition, we are considering seeking collaboration partners for overseas trials for FT-003 and other pipeline products. The FDA has approved Phase II clinical trials in both nAMD and DME for FT-003 in the United States.

Continue to enhance our CMC and manufacturing capacities to support eventual commercialization

In light of the progress of FT-002 and FT-003 through clinical development, we will further optimize our production processes, verify our testing methods, and conduct process validation in preparation for commercial-scale manufacturing. We will continue to enhance our AAVANCE™ technology with process automation to maintain high purity and lower per-dose manufacturing cost and may consider opportunities to license out our AAVANCE™ manufacturing technology to partners as an additional revenue stream. We will upgrade our facilities as necessary whether in terms of hardware, software or personnel to ensure compliance with evolving quality standards as well as procedural onsite inspections from regulatory bodies prior to receiving market approval. We will also continue to reinforce our robust quality control system, benchmarking it against the highest international standards adopted by pharmaceutical multinational corporations, to achieve patient safety and regulatory compliance.

Continue to build up our EXACTE™ development platform to expand our coverage to other underserved indications and fully realize the clinical and commercial value of our technology platforms

We intend to further strengthen the capabilities of our EXACTE™ platform in a variety of aspects including capsid design, payload optimization and lead drug candidate screening. Some examples might include further developing capsids for better intravitreal injection and for better cardiovascular targeting while de-targeting other tissues, as well as further engineering the recombinant baculovirus genome to improve our recombinant baculovirus genome stability. We plan to leverage our EXACTE™ platform to further advance the preclinical and early-stage assets in our pipeline for ophthalmic and cardiovascular diseases. In addition, we aim to leverage our gene therapy know-how to expand to other therapeutic areas and indications in order to enlarge our target market and benefit a larger patient population.

Implement tailored commercialization approaches for different indications to fully achieve commercial and clinical benefits

We plan to adopt a flexible commercialization strategy in China, combining an in-house sales force with professional partners to achieve optimal market penetration. For products addressing rare diseases, we aim to establish an in-house sales team and capitalize on collaboration with third parties. We would also consider how to utilize favorable policies, such as within selected industry Pilot Zones in China where certain treatments are allowed before NMPA approval. For products addressing large-market diseases, particularly in overseas markets, we anticipate seeking commercialization partners with local knowledge and connections in various markets to reach the larger patient pool.

Continue to carry out our global strategy by pursuing overseas clinical development and commercialization through collaborations and partnerships

We intend to adhere to our global operation strategy through both clinical development and commercialization, to reach a larger addressable market and benefit patients worldwide with our solutions. On the commercialization front, we will seek to explore strategic partnerships to achieve swift entrance into overseas markets. These efforts might include out-licensing agreements to allow global biopharma partners to conduct clinical studies on our pipeline assets and commercialize approved products in overseas jurisdictions to expand

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our addressable market. We will also evaluate opportunities to collaborate with global pharmaceutical companies to leverage our platform and expand our portfolio for the global market.

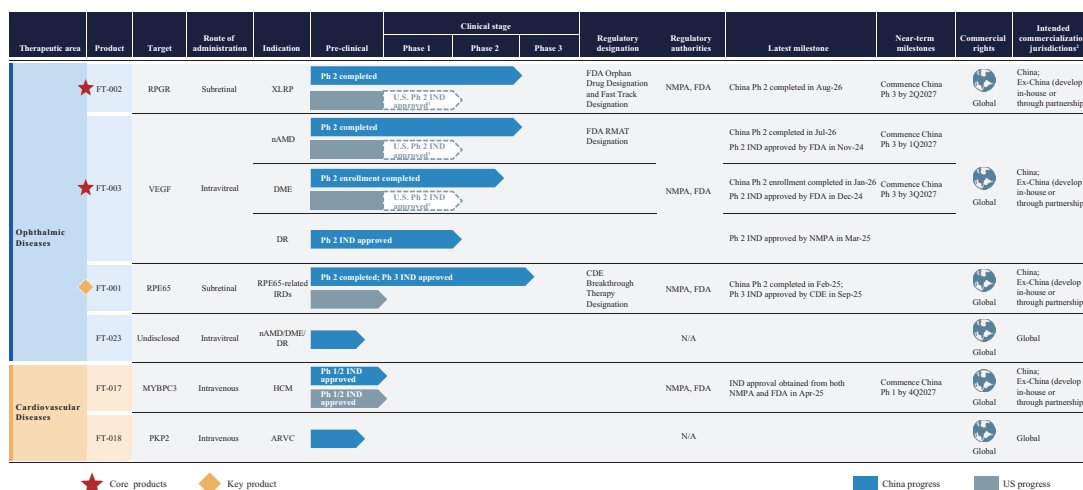
Cultivate and retain talent to transform human capital into the catalyst for sustained innovation and shareholder value creation

Over the next few years, we intend to expand our existing team across R&D, clinical science, medical and regulatory functions. We will continue to attract and retain globally competitive talent while embedding systematic training, performance evaluation and leadership development programs. As our clinical drug candidates advance towards approval, we also intend to build an in-house sales team to support commercialization needs after market launch.

Pipeline Overview

As of the Latest Practicable Date, our product pipeline consisted of six in-house developed rAAV gene therapy candidates, including (i) two Core Products, namely FT-002, a drug candidate being investigated to treat XLRP, and FT-003, a drug candidate being investigated to treat nAMD and DME through intravitreal injections; (ii) one Key Product, namely FT-001, a gene therapy drug candidate for treating IRD caused by biallelic mutations in the RPE65 gene; and (iii) three other preclinical and early-stage gene therapy drug candidates for the treatment of ophthalmic and cardiovascular diseases.

The following chart shows the pipeline of gene therapies we have under development:



Pipeline Strategies

Our pipeline strategies are designed to address primarily large-market or currently untreatable diseases with effective, safe, and affordable rAAV gene therapy solutions. Unlike traditional gene therapy companies that generally focus on inherited or rare diseases, we are committed to developing drug candidates for large-market indications. For inherited diseases, our focus is on those that currently lack effective treatments.

- Strategic Focus on Large-market or Currently Untreatable Diseases:** Ophthalmic diseases — owing to the localized delivery options, immune-privileged environment, and unmet medical needs — have emerged as a promising area for gene therapy. We are targeting nAMD and DME — refractory conditions that collectively affect millions worldwide and are leading causes of vision loss, representing a large market potential. For inherited diseases, we are advancing a therapy for XLRP, a major cause of middle-age blindness for which no treatment is currently available. Building on our experience in ophthalmic diseases, we are

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also expanding into cardiovascular diseases, targeting diseases such as HCM and ARVC, all of which have significant unmet needs and large market potential.

- **Approaches:** We aim to develop gene therapies that are safe, effective, and convenient for patients at an affordable cost. Our innovation in AAV capsid selection and genetic payload design emphasizes safety and effectiveness. FT-003, our Core Product for nAMD and DME, offers the convenience of a one-time intravitreal injection and has shown sustained improvements in visual acuity and retinal structure, together with a markedly reduced treatment burden compared with the current standard-of-care anti-VEGF therapy over three years. FT-002, our Core Product for XLRP, has demonstrated sustained improvements in visual function, retinal structure, and vision-related quality of life over two years till the latest data cut-off date. FT-002 has been granted Orphan Drug Designation and Fast Track Designation by the FDA, and FT-003 has been granted the RMAT designation by the FDA.
- **Commitment to Affordable Therapies:** We are dedicated to improving access to gene therapy through competitive production costs and affordable pricing. To our knowledge, we are among the few gene therapy-focused biotech companies globally, and the first in China, to establish commercial-scale Bac/Sf9-based rAAV manufacturing, which provides a meaningful cost advantage for future commercialization. For example, FT-001 achieves as much as a 90% reduction in direct production cost, by our estimate, compared to the only gene therapy treatment option approved in the United States and Europe for the target disease of FT-001. This significant cost advantage enables us to deliver more affordable gene therapies and expand market accessibility.
- **Emphasis on Product Quality and Safety:** Our EXACTE™ R&D platform integrates vector designs and advanced *in vitro* and *in vivo* screenings to select candidates with optimal tissue tropism, high transduction efficiency, and durable expression. Meanwhile, our AAVANCE™ manufacturing platform achieves industry-leading yields with upstream yield of more than 10^{15} vg/L, while laboratory-scale rAAV production typically achieves yields in the range of 10^{12} – 10^{14} vg/L. Our system also accomplishes exceptionally low empty capsid rates of less than 1%, whereas the industry norm is close to 30%.
- **Operational Excellence and Global Accessibility:** Our footprint spanning China and the United States enables precise indication selection, well-designed clinical programs, and efficient participant recruitment. It has taken us as little as 11 months to advance a drug candidate from lead identification to IND approval, demonstrating our highly efficient execution capabilities and cross-regional collaboration. We are the first Chinese rAAV gene therapy company using a Bac/Sf9 system to obtain IND approval from the FDA for a Phase II clinical trial based on CMC, preclinical, and Phase I clinical data generated in China, according to Frost & Sullivan. We retain full global rights to our pipeline, allowing us to pursue direct commercialization or strategic partnerships to maximize global market potential.

As there are various risks specific to gene therapies, relating to the irreversible nature of gene therapies, unintended side effects, and risks of delayed adverse events, we take the safety of our product candidates seriously and strictly abide by applicable regulatory requirements relating to the clinical development of gene therapies. As further discussed below, our Core Products and Key Product have demonstrated favorable safety and tolerability profile based on the latest available clinical data, and we conduct up to five years of long-term follow-up to monitor long-term safety profiles of our drug candidates.

As of the Latest Practicable Date, the five-year long-term follow-up period for our drug candidates has not impacted, and is not expected to impact, its development, registration or commercialization. Based on our current development plans and disclosed program timelines, such long-term follow-up is being conducted in parallel with our ordinary course research and development activities and is not a prerequisite to advancement to the next stage of development. For AAV gene therapy products, the required five-year long-term follow-up comprises a one-year clinical trial observation period after dosing and an additional four years of follow-up. In accordance with the Technical Guidelines for Long-term Follow-up Clinical Research of Gene Therapy Products (Trial) (《基因治療產品長期隨訪臨床研究技術指

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導原則（試行）》) issued by the CDE of the NMPA pursuant to Announcement No. 50 of 2021, which contemplates that subjects receiving gene therapy products may not have completed the full long-term follow-up period at the time of marketing approval and that continued long-term safety monitoring may be conducted after approval, a BLA may be submitted upon completion of the one-year clinical trial observation period on the basis of the efficacy and safety data generated during that period. This is also consistent with the approval pathway observed for certain gene therapy products in China and overseas jurisdictions. Accordingly, the subsequent long-term follow-up period does not affect, and is not expected to affect, the regulatory review or commercialization process for our drug candidates.

OUR DRUG CANDIDATES

FT-002, an rAAV gene therapy for XLRP, our Core Product

Overview

FT-002 is a gene therapy drug candidate and is currently the only clinical-stage rAAV gene therapy being developed for XLRP in China. XLRP is one of the most severe forms of IRD primarily caused by mutations in the RPGR gene. The disease is characterized by progressive and irreversible vision loss, typically presenting before the age of 10 and progressing to legal blindness before the age of 50. There are currently no approved therapies available for XLRP worldwide.

We have completed Phase I clinical trials in China in August 2024 and Phase II clinical trials in China in August 2026. In the United States, FT-002 was granted Orphan Drug Designation in January 2024, we received clearance for Phase II clinical trials in September 2024, and FT-002 was granted Fast Track Designation in October 2024.

Drug Design and Mechanism of Action

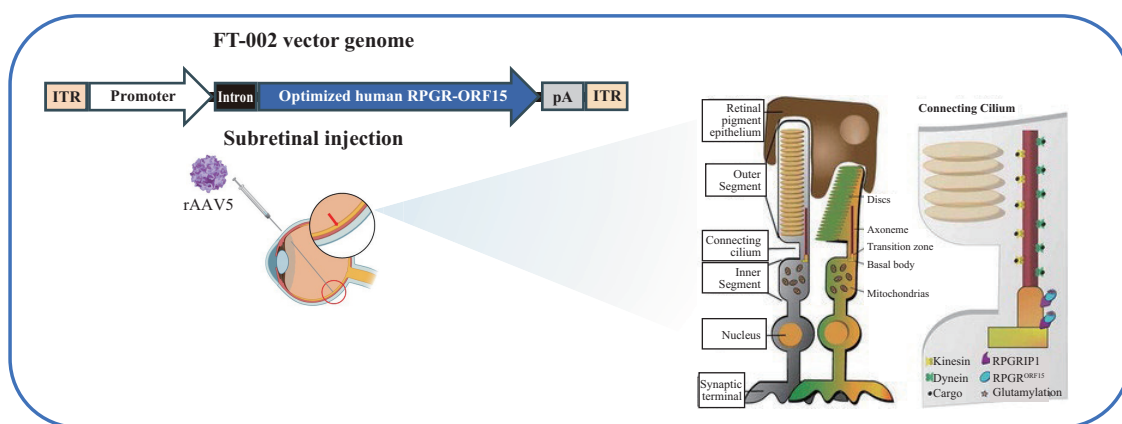
The retinitis pigmentosa GTPase regulator (“**RPGR**”) gene encodes the RPGR protein, which plays a key role in the transport of proteins within the connecting cilium of photoreceptor cells — specialized cells in the retina responsible for capturing light and initiating vision. The connecting cilium acts as a bridge between the inner and outer segments of photoreceptors, facilitating the movement of essential proteins and materials required for photoreceptor survival and function. Mutations in the RPGR gene, especially in the ORF15 region, disrupt this transport process, leading to the mislocalization of critical visual proteins, degeneration of photoreceptor cells, and progressive vision loss.

FT-002 aims to rescue the functional and/or structural loss of the photoreceptor cells due to the RPGR gene mutations by delivering a functional copy of the RPGR-ORF15 gene, enabling the production of functional RPGR protein, and thereby correcting the cellular transport defects that lead to retinal degeneration and vision loss in XLRP patients. This approach represents a promising strategy for treating a currently untreatable blindness-causing genetic disease. Specifically, FT-002 utilizes a recombinant adeno-associated virus serotype 5 (“**rAAV5**”) as a delivery vehicle, or “vector.” This vector is engineered to carry a codon-optimized, full-length human RPGR-ORF15 gene. Codon optimization is a process that modifies the genetic code to enhance the efficiency and stability of gene expression in human cells, ensuring that the therapeutic protein is produced at sufficient levels.

FT-002 is administered via a single subretinal injection — a targeted delivery directly beneath the retina. This approach allows the rAAV5 vector to efficiently transduce the photoreceptor cells. Once inside the cell, the vector delivers the full-length RPGR-ORF15 gene to the cell nucleus, where it is transcribed and translated into the RPGR protein. The newly produced RPGR protein restores the normal function of connecting cilium in photoreceptor cells. Specifically, it re-establishes the proper transport of proteins and other molecules between the inner and outer segments of the photoreceptors. This helps to maintain the structural integrity and function of these cells, preventing further degeneration and potentially improving or stabilizing visual function.

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The following diagram illustrates the mechanism of action of FT-002:



Note: ITR = inverted terminal repeats; pA = polyadenylation signal.

Source: Literature Review

Market Opportunities and Competition

XLRP is one of the most severe and prevalent subtypes of IRD, a group of progressive, irreversible retinal degenerative disorders caused by genetic mutations. According to Frost & Sullivan, IRD collectively affects 5 to 10 million patients worldwide. Retinitis pigmentosa (“RP”) is the most common IRD, with over 1.5 million patients globally. RP can be inherited in autosomal recessive, autosomal dominant, or X-linked patterns, with XLRP accounting for approximately 5% to 15% of all RP cases and representing a major cause of mid-age blindness.

XLRP typically has early onset and rapid progression, leading to severe vision loss or blindness by middle age. Symptoms appear around the age of 10, leading to narrow visual fields and early nyctalopia and typically progressing to legal blindness before the age of 50. There are 62.3 thousand XLRP patients in China and 15.3 thousand XLRP patients in the United States in 2025.

Traditional management is limited to lifestyle adjustments and nutritional support, which do not halt or reverse disease progression. To date, there are no approved therapies for XLRP, creating a substantial unmet medical need and a highly attractive market opportunity.

FT-002 is currently the only clinical-stage XLRP gene therapy product in China and one of the most advanced globally. FT-002 has received Orphan Drug Designation and Fast Track Designation from the FDA, underscoring its global innovation and clinical value. We believe FT-002 is well positioned to capture significant market share both in China and internationally. As genetic diagnostics and patient identification improve, the addressable market is expected to expand further. FT-002’s potential success would mark a milestone for gene therapy in XLRP and the broader IRD field.

As of the Latest Practicable Date, there are three rAAV gene therapy drug candidates in the process of clinical development for the treatment of XLRP globally, FT-002 and laru-zova. The following chart illustrates the global competitive landscape of FT-002 as of the Latest Practicable Date, according to Frost & Sullivan:

Drug Name	Company	Target	Vector type	Clinical Stage	First Posted Date	Country	Manufacturing System
Botaretigene sparaparvovec ¹	MeiraGTx	RPGR	AAV5	Phase III	2020-12-17	US, UK, Spain, etc.	HEK293
Laruparetigene zosaparvovec (laru-zova, AGTC-501)	Beacon Therapeutics	RPGR	AAV2	Phase II/III	2021-04-20	UK, US, Australia	HSV/BHK ²
FT-002	Frontera Therapeutics	RPGR	AAV	Phase II	2024-10-15 ³	China	Bac/Sf9
				Phase II IND Approval	2024-09-23	U.S.	

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Notes:

- (1) Botaretigene sparaparvovec was originally licensed to J&J in 2019 and was sold to them in 2023 for up to \$415M; it was reacquired by MeiraGTx in 2026 for \$25M after its Phase 3 trial missed the primary endpoint. As of the Latest Practicable Date, MeiraGTx plans regulatory filings in the US, EU, UK and Japan in 2026, targeting a 2027 launch.
- (2) As of the Latest Practicable Date, in the field of rAAV gene therapy, the HSV/BHK system has not been validated with any drug approval globally.
- (3) FT-002 has completed both Phase I and Phase II clinical trials. The first posted date disclosed herein refers to the date on which the first participant in the Phase II trial signed the informed consent form.

Source: Clinicaltrial.gov, CDE, Frost & Sullivan Analysis

Key Advantages

FT-002 would be a significant advance in the treatment of XLRP. As the first and only clinical-stage rAAV gene therapy for XLRP in China — and one of the most advanced globally — FT-002 is well positioned to address this severe, inherited condition that is currently untreatable.

- **Only Clinical-Stage rAAV Gene Therapy for XLRP in China.** FT-002 is the first and only clinical-stage rAAV gene therapy product for XLRP in China, and among the most advanced globally. It has received Orphan Drug Designation and Fast Track Designation from the FDA, underscoring its global innovation and clinical value. If approved, FT-002 would address a significant unmet medical need for XLRP patients, for whom no approved therapies currently exist.
- **Drug Design for Efficacy and Safety.** FT-002 is engineered to deliver a full-length, codon-optimized human RPGR-ORF15 gene, which is essential for restoring the function of photoreceptor cells in XLRP patients. The use of a codon-optimized sequence ensures efficient and stable gene expression, maximizing the production of functional RPGR protein and supporting long-term restoration of visual function. The gene is packaged within an AAV5 capsid, selected for its strong tropism for photoreceptor cells, enabling highly efficient and targeted gene delivery to the retina. The gene expression cassette incorporates a carefully selected promoter, an intron, and polyadenylation elements to drive robust and sustained transgene expression. CpG motif optimization is also included to minimize immunogenicity, enhancing the overall safety profile of the therapy. Subretinal administration further ensures that the therapeutic gene reaches the appropriate retinal layers for optimal effect and avoids off-target toxicity.
- **Demonstrated Clinical Efficacy and Long-Term Benefit.** Collectively, clinical data from our investigator-initiated trials and Phase I/II clinical trials consistently demonstrate that FT-002 provides clinically meaningful and sustained improvements in visual acuity, retinal sensitivity, and quality of life, with a favorable safety profile in both adult and pediatric XLRP participants. These results underscore the potential of FT-002 to deliver long-term clinical benefit for XLRP patients.
 - o In the Phase I clinical trial, adult participants in the high-dose group of FT-002 experienced meaningful gains in both best corrected visual acuity (“BCVA”) and retinal sensitivity over one year. These improvements were accompanied by positive changes in participant-reported quality of life, as measured by standardized questionnaires. Imaging studies further supported these findings, revealing preservation or restoration of retinal structure, suggesting a slowing of disease progression.
 - o In the Phase II clinical trial, for up to the longest follow-up of 12 months, all pediatric participants demonstrated marked improvements in low luminance visual acuity (“LLVA”) and microperimetry, indicating enhanced visual acuity and retinal function.
- **Favorable Safety Profile and Attractive Cost Efficiency.** Preclinical and clinical studies have demonstrated a comparable safety and tolerability profile of FT-002 compared with the only other gene therapy candidate for XLRP under clinical development globally, with no DLT or FT-002-related SAEs observed. We manufacture FT-002 using a Bac/Sf9 system, which enables low empty capsid rates and a highly competitive reduction in production costs, supporting broader patient access and commercial viability.

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- **High Probability of Success and Global Commercial Potential.** With its design, robust preclinical and clinical data, FT-002 is well positioned for early commercialization in China and internationally. The therapy’s safety and efficacy, combined with its cost-effective manufacturing, supports its potential to capture significant market share and benefit patients with XLRP worldwide.

Summary of Clinical Trial Data

Investigator Initiated Trial

We worked with Prof. Ruifang Sui at the Peking Union Medical College Hospital and Prof. Gezhi Xu at the Eye & Ent Hospital of Fudan University, respectively, for the investigator-initiated trial of FT-002. We collaborated with the hospitals as they had applicable clinical research qualifications, leading experts in the field, and access to a large patient pool.

Based on the terms of our collaboration agreement, we are responsible for supplying the drugs required and bearing all expenses associated with the investigator-initiated trial, which were funded by our working capital. During the Track Record Period, we incurred a total of US\$0.4 million in professional services expenses associated with the trial and expect to incur an additional US\$0.2 million. The investigator was primarily responsible for designing the trial protocol and its execution. There is no explicit confidentiality provision in our collaboration agreement.

We had five patent applications for FT-002, including one of the patent applications in the United States that received a notice of allowance in May 2026, which cover all known key features and/or characteristics of FT-002, and have not received any material concerns or inquiries from relevant competent authorities relating to the applications. The investigators have not filed, and have confirmed in writing that they will not file, any patent applications relating to FT-002. Based on advice from our IP counsel, we are of the view that (i) as we have filed the FT-002 composition of matter patent in a complete form more than 18 months before the investigator-initiated trial began, and FT-002 was not modified during the investigator-initiated trial, the investigator-initiated trial (and the investigator’s participation therein) should not affect our FT-002 patent; and (ii) even if the investigators are to file a patent application relating to FT-002 contrary to their written confirmation, such application will be rejected by the patent offices as the Company has commenced clinical trials on FT-002 which have been published in the public domain. We did not rely on the results of the investigator-initiated trial for obtaining the IND approval for FT-002 from NMPA, since the investigator-initiated trial was concluded in November 2024 and we, as the sole sponsor, submitted the IND application for FT-002 in August 2023 and obtained approval in November 2023. We solely own all patent applications in connection with FT-002 filed by us, and have not out-licensed such pending patents to a third party. We are of the view that there are no valid third party patents enforceable against us in connection with FT-002. Thus, we believe we have full and independent rights to conduct R&D and commercialization of FT-002.

Trial design. The investigator initiated trial of FT-002 was an open-label, dose-escalation trial in adult males aged 18 to 45 years with RPGR mutation-associated XLRP. A total of 18 participants were evenly enrolled. Three dose cohorts were established, including (i) low-dose group: 5×10^{10} vg/eye; (ii) medium dose group: 1.0×10^{11} vg/eye; and (iii) high-dose group: 2.0×10^{11} vg/eye.

Trial objectives. The primary objective was to evaluate the safety, tolerability and efficacy at a single subretinal injection of FT-002 in participants with XLRP.

Trial status. The IIT study was initiated in February 2023 and completed its 52-week follow-up in November 2024. All participants are undergoing five years of long-term follow-up.

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Safety and Efficacy data. Up to the longest follow-up of three years, there were no observed DLT, FT-002 related SAEs, RPE atrophy, or macular thinning. Most TEAEs related ocular inflammation were related to the surgical procedure, and were controllable through topical use of steroids. In addition, the IIT data demonstrated improvements in retinal function and vision-related quality of life, with stable visual acuity.

Phase I Clinical Trial

Trial design. The dose escalation Phase I clinical trial of FT-002 was an open-label study in adult male participants aged 18 to 45 years with RPGR mutation-associated XLRP. The trial enrolled a total of seven participants, with each participant receiving a single subretinal injection of FT-002 in one eye. Three dose cohorts were established, including (i) low-dose group: 0.33×10^{11} vg/eye, which enrolled one participant; (ii) medium-dose group: 1.0×10^{11} vg/eye, which enrolled three participants; and (iii) high-dose group: 2.0×10^{11} vg/eye, which enrolled three participants.

Key inclusion criteria for the trial include but are not limited to (i) male participants aged 18 to 45 years old, (ii) clinically diagnosed with XLRP, (iii) confirmed mutations of the RPGR gene based on genetic tests, (iv) BCVA of no lower than 34 letters and no more than 78 letters for the fellow eye, and BCVA of no less lower than 19 letters for the fellow eye, and (v) a detectable sub-foveal ellipsoid zone assessed by OCT or residual visual field within 30° by static perimetry in the study eye. Key exclusions criteria for the trial include but are not limited to (i) participants have other retinal diseases such as IRD which may affect the assessment of trial results, (ii) participants had relevant treatment record and/or allergies, including recent eye surgeries, other gene therapy treatments, or allergies to materials used in the trial, and (iii) participants have systemic risks such as high blood pressure.

After receiving FT-002, all participants completed 28 days of observation to determine DLT, and, according to the requirement and authorization of the CDE-approved trial protocol, an independent data monitoring committee (“iDMC”) meeting, comprising of a group of independent experts, was held to review the safety and tolerability data of all participants to confirm the initiation of the Phase II dose-expansion study. Meanwhile, all seven participants were expected to complete 52 weeks of follow-up unless they withdrew early, and entered the long-term follow-up period until 5 years after injection to evaluate the long-term safety and efficacy.

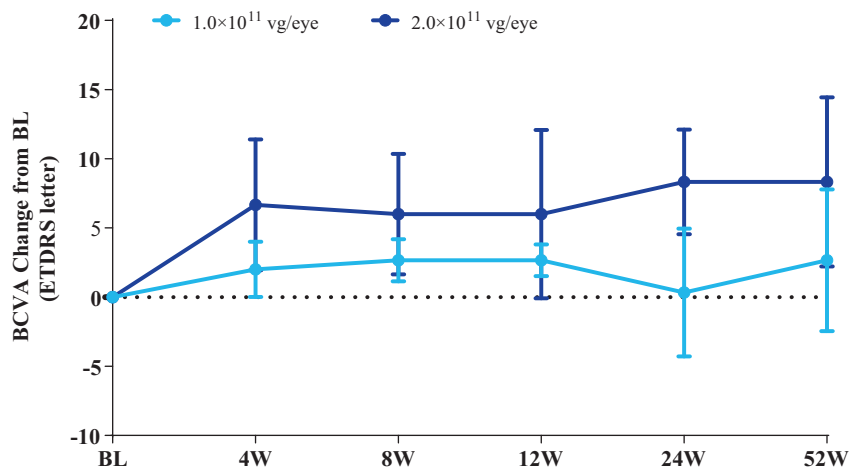
Trial objectives. The objective was to evaluate the safety, tolerability and preliminary efficacy of a single subretinal injection of FT-002 in participants with XLRP. Primary endpoints relate to safety and tolerability, and include DLT within 28 days and incidents of AEs and SAEs. Secondary endpoints relate to efficacy, including changes in BCVA from baseline, and immunogenicity and AAV shedding, within 52 weeks.

Trial status. The clinical trial was initiated in April 2024 and was completed in August 2024 following the completion of 28-day observation. The iDMC meeting then evaluated the primary endpoints, which are the only prerequisites for the initiation of Phase II clinical trials, and confirmed this initiation. No communication with the CDE is required to confirm whether the primary or secondary endpoints were met until we propose to initiate the Phase III clinical trials. Furthermore, 52-week follow-up was completed in September 2025, in which the results have met our trial objectives regarding secondary endpoints. All participants are undergoing five years of long-term follow-up.

Efficacy data. The results of the Phase I clinical trial indicated that participants receiving high-dose FT-002 demonstrated sustained improvements in visual acuity, retinal function and structure, as well as vision-related quality of life. In the high-dose group, the BCVA improvement was 8.3 ± 6.11 letters, with 33.3% of participants gained more than 15 letters. Improvements in BCVA of no less than 5 letters is deemed the minimal clinically important difference, and improvements of no less than 15 letters is deemed to clinically significantly improve vision. The high dose group’s improvements in BCVA, especially sustained over 52 weeks, indicate that FT-002 restores or preserves central vision. As illustrated in the diagram below, participants receiving high-dose FT-002 experienced

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sustained improvements in BCVA. No meaningful improvement in BCVA were observed for the low-dose and medium-dose groups.



Source: Company data

For comparison, BCVA changes were also evaluated for the non-treated fellow eye, which generally experienced less significant improvements from baseline during the observation and follow-up period.

At Week 52, the change from baseline in vision-related quality of life (NEI VFQ-25 score) in the high-dose group was an increase of 14.139 ± 9.560 points. For the low and medium-dose groups, changes from baseline was an increase of 9.3494 points and a decrease of 3.977 ± 9.770 points, respectively. The NEI VQ-25 score refers to scoring on a standard participant-reported questionnaire assessing vision-related quality of life across 12 domains, with scores from 0 to 100. An improvement of 6 points or above is statistically significant and represents changes that are very likely tangible to the participants and positively contribute to their quality of life. In this case, the increase of 14.139 ± 9.560 points for the high-dose group demonstrates significant clinical value of FT-002.

Importantly, OCT results showed that, in the high-dose group, the mean ellipsoid zone (“EZ”) width in the study eye increased by 0.022 ± 0.146 mm from baseline at Week 52. For the low and medium-dose groups, changes from baseline was a decrease of 0.096 mm and a decrease of 0.136 ± 0.068 mm, respectively. Compared with an average EZ width decrease of 0.173 to 0.289 mm per year in natural history studies of XLRP, an increase in EZ width after FT-002 treatment for the high-dose group suggests preservation or restoration of retinal structure, indicating the slow down or reverse the disease progression.

Safety data. The results of the Phase I clinical trial indicated that the overall safety and tolerability of FT-002 was favorable. No DLTs or FT-002-related SAEs were observed. Three participants (including two in the medium-dose group and one in the high-dose group) reported FT-002-related ocular TEAEs in the severity of Grade 2, including vitritis and iritis, which were resolved after treatment with steroid eye drops. One participant in the medium-dose group experienced SAE in the severity of Grade 3, which was an anal abscess, and was assessed to be unrelated to FT-002 and surgical procedure. There was no adverse event that led to patient withdrawal or study discontinuation.

With respect to AAV shedding within 52 weeks, transient and low levels of FT-002 vector genomic DNA were detected in the peripheral blood, urine and tears from both eyes of the participants, while no significant or sustained AAV shedding was observed.

Phase II Clinical Trial

Trial design. The dose expansion Phase II clinical trial of FT-002 was a single-dose, open-label clinical trial targeting (i) pediatric participants aged 8 to 17 years and (ii) adult

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participants, with RPGR mutation-associated XLRP. Each enrolled participant received a one-time subretinal injection of FT-002 in a single eye. The recommended Phase II dose (RP2D) of 2.0×10^{11} vg per eye was determined based on the safety and efficacy data from the Phase I clinical trial.

Key inclusion criteria for the trial include but are not limited to (i) participants must be either pediatric participants aged 8 to 17 years old or adult participants aged 18 to 40 years old, (ii) clinically diagnosed with XLRP, (iii) confirmed mutations of the RPGR gene based on genetic tests, and (iv) BCVA of no lower than 34 letters and no more than 78 letters. Key exclusions criteria for the trial are generally the same as the criteria for the Phase I clinical trial.

After receiving FT-002, the 6 pediatric participants completed 52-weeks of follow-up and the 5 adult participants completed 24-weeks of follow-up to assess the safety, efficacy and immunogenicity of FT-002. Participants have entered long-term follow-ups up to 5 years after completing the Week-52 visit, which will be conducted every 6 month, to evaluate the long-term safety and efficacy of FT-002.

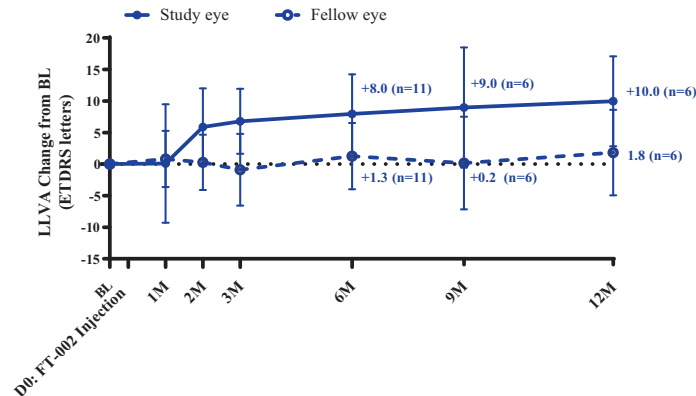
Trial objectives. The primary objective was to evaluate the safety, tolerability and efficacy of a single subretinal injection of FT-002 at RP2D in both pediatric and adult XLRP participants. Primary endpoints relate to efficacy, and include changes in low luminance visual acuity (“LLVA”) from baseline. Secondary endpoints relate to efficacy, including changes in BCVA from baseline, safety, immunogenicity and AAV shedding.

Our trial protocols previously listed changes in mean retinal sensitivity (MS) from baseline as a primary endpoint, and changes in LLVA from baseline as a secondary endpoints. In July 2026, to align with the efficacy endpoints of other XLRP-targeting gene therapy drugs in advanced clinical stages, we amended our trial protocols to remove changes in MS from baseline as a primary endpoint and added changes in LLVA from baseline as a primary endpoint. This amendment was reviewed and approved by an ethics committee, comprising of independent industry experts, which is responsible for reviewing any amendment to the pre-approved trial protocol.

Trial status. This Phase II clinical trial was initiated in February 2025, and completed the enrollment of six pediatric participants in July 2025 and five adult participants in March 2026. In August 2026, the Phase II clinical trial was completed as the six pediatric participants have completed 52 weeks of follow-up and the five adult participants have completed 24 weeks of follow-up. All endpoints have been assessed and are expected to be submitted to the CDE for evaluation in the third quarter of 2026. We expect to obtain a no-objection confirmation from the CDE in the fourth quarter of 2026 and initiate Phase III clinical trial by the second quarter of 2027.

Efficacy data. Based on 24-week follow-up data for both of the adult and pediatric cohorts and 52-week follow-up data for the pediatric cohort and: (i) for both of the adult and pediatric cohorts, the study eye of each adult participant demonstrated an improvement in LLVA, with an average increase of 8.0 letters from baseline at Week 24, compared to an average increase of 1.3 letters in the fellow eye and (ii) for the pediatric cohort, the study eye of each pediatric participant demonstrated a sustained improvement in LLVA, with an average increase of 10.0 letters from baseline at Week 52, compared to an average increase of 1.8 letters in the fellow eye. LLVA measures cone function under low luminance (2.0 log filter). In XLRP, LLVA is a critical measure of visual function, and a gain of more than 10 letters is considered to be clinically significant. The following diagram illustrates LLVA changes from baseline for both the study eye and fellow eye.

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Source: Company data

Safety data. Based on 52-week follow-up data for the pediatric cohort and 24-week follow-up data for the adult cohort, all participants demonstrated good tolerability and safety. No ocular SAEs, SUSARs or FT-002 related ocular inflammations were reported. There was also no Grade 3 or above AEs. There was no adverse event that led to patient withdrawal or study discontinuation. Importantly, compared to adult participants, the 6 pediatric participants did not experience any new safety signals over the extended 52-week follow-up period. The incidence and severity of FT-002-related adverse events in both age groups were comparable to those observed in prior studies.

With respect to AAV shedding in pediatric participants, transient and low levels of FT-002 vector genomic DNA were detected in the peripheral blood, urine and tears from both eyes, while no significant or sustained AAV shedding was observed.

Material Communications and Next Steps

We received IND approval from the NMPA in November 2023, which covered both a dose escalation Phase I and a dose expansion Phase II clinical trial as two distinct segments. We did not receive comments from the NMPA to our clinical trial plans before receiving the IND approval. Pursuant to the IND approval, we initiated and completed the Phase I clinical trial in April 2024 and August 2024, respectively, according to the trial design, and initiated the Phase II clinical trial in February 2025.

Taking into account the industry practice as advised by Frost & Sullivan, the dose escalation Phase I clinical trial constituted a completed clinical trial with its main purpose aligning with the overall purpose of a conventional Phase I clinical trial, which is typically to assess safety and determine the dosage for Phase II clinical trial. On November 11, 2015, the CFDA issued the Announcement on Certain Policies for Drug Registration, Evaluation and Approval (the “**Announcement for Drug Approval**”) (關於藥品註冊審評審批若干政策的公告), which regulates that an umbrella approval would be issued by the NMPA for multiple phases of a new drug clinical trial, instead of approvals phase by phase, based on the above and FT-002 clinical trial protocols submitted to the CDE, our PRC Legal Advisor is of the view that we are not required to obtain additional regulatory approval from the NMPA for commencing the dose expansion Phase II clinical trial in China. In December 2025, we consulted the Yangtze River Delta Center of the CDE (國家藥品監督管理局藥品審評檢查長三角分中心) regarding the commencement of our Phase II clinical trial after completion of the Phase I clinical trial. We reached a representative of the Yangtze River Delta Center from their official consultation hotline, which, as confirmed by our PRC Legal Adviser, (i) is an official channel for consultation with the CDE on the matters regarding drug evaluation, including the application for drug clinical trials, and (ii) as such hotline is the official channel for consultation with the CDE, the representative who received the call is the qualified person to respond to public inquiries. According to Frost & Sullivan, it is also customary for companies in China to seek the CDE’s official views through the CDE’s official consultation hotline. We informed the representative of details of our clinical trials including the fact that

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our IND covered both a Phase I and a Phase II clinical trial and that the clinical trials do not have components outside of China. Based on our explanations, the representative confirmed that we are not required to obtain additional regulatory approval from the NMPA for commencing the Phase II clinical trial in China and expressed no objection for us to commence the Phase II clinical trial of FT-002.

In January and October 2024, FT-002 was granted Orphan Drug Designation and Fast Track Designation by the FDA, respectively. In September 2024, the FDA has approved the Phase II clinical trial for FT-002 in the United States, making us the first Chinese rAAV gene therapy company using a Bac/Sf9 system to obtain IND approval from the FDA for a Phase II clinical trial. Our application materials for the Phase II clinical trial included CMC, preclinical, and Phase I clinical data generated in China, as well as proposed Phase II clinical trial plan in the U.S. Before granting its IND approval, the FDA raised comments primarily regarding the enrolled participants, follow-up approaches, and efficacy endpoints, and we made corresponding changes to the Phase II trial plan accordingly. The FDA’s approval for the Phase II clinical trial despite the absence of a completed Phase I clinical trial in the United States was based on CMC, preclinical, and Phase I clinical data generated in China. The scope of the IND approval from the FDA covered the Phase II study to investigate efficacy and safety of subretinal injection of FT-002 in participants with RPGR-associated XLRP.

To date, the NMPA and the FDA have not raised any objections or material concerns with respect to the development of FT-002.

The Phase II clinical trial of FT-002 initially targeted pediatric participants aged 8 to 17 years with RPGR mutation-associated XLRP. In September 2025, we made a submission to the CDE to discuss Phase III clinical trial plans of FT-002, which included our then available Phase II clinical trial results, and received feedback in December 2025 that recommended (i) completing 52 weeks of follow-up for the pediatric participants before evaluating the initiation of the Phase III trial and (ii) considering the applicability of the clinical trial results of pediatric participants with respect to the proposed enrollment of adult participants in the Phase III trial. Following such recommendations, we voluntarily amended the Phase II clinical trial protocol, with the CDE’s agreement, to include an additional three to six adult participants. As of the Latest Practicable Date, we have completed Phase II clinical trials for FT-002 in China, with a total of six pediatric participants who have completed 52 weeks of follow-up and five adult participants who have completed 24 weeks of follow-up. All endpoints have been assessed and the results are expected to be submitted to the CDE for evaluation in the third quarter of 2026. We expect to obtain a no-objection confirmation from the CDE in the fourth quarter of 2026 and initiate Phase III clinical trial by the second quarter of 2027. Save for the communications discussed above, we have not received any comments from the CDE in relation to the clinical trial results of FT-002.

We will also continue pursuing development and approval for FT-002 in the United States, leveraging its Orphan Drug Designation and Fast Track Designation status. We currently expect to pursue further clinical development in the U.S. leveraging clinical data from China and in collaboration with local CROs at appropriate times. We intend to submit an application for the FDA’s regenerative medicine advanced therapy (RMAT) designation for FT-002 in the fourth quarter of 2026 and seek a pre-Phase III meeting by the first quarter of 2027. Subject to applicable regulatory approvals, we intend to commence Phase III clinical trial of FT-002 in the United States by the end of 2027. We believe we have sufficient R&D capability in the U.S. to progress the clinical development of FT-002 through collaboration with local CROs. We will flexibly adjust our resource allocation between progressing the clinical trials in China and the United States, as well as the desired pace of clinical development, based on the local regulatory and market environment in these jurisdictions, the competitive landscape, and the abundance of our own resources. In doing so, we fully intend to take advantage of the FDA approval for Phase II clinical trials in the United States and the Orphan Drug Designation and Fast Track Designation status of FT-002 to unlock the greatest market potential and maximize value to stakeholders.

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FT-002 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

FT-003, an rAAV gene therapy for nAMD and DME, our Core Product

Overview

FT-003 is an intravitreal rAAV gene therapy drug candidate being investigated for nAMD and DME. These retinal vascular diseases are among the leading causes of vision loss and blindness worldwide, particularly affecting the elderly and individuals with diabetes. Current standard-of-care therapies for nAMD and DME rely on frequent intravitreal injections of anti-VEGF agents, which impose a substantial, cumulative treatment burden on patients and healthcare systems, often resulting in suboptimal compliance and poor long-term outcomes.

FT-003 is the most advanced intravitreal gene therapy for nAMD in China in terms of clinical development progress, according to Frost & Sullivan. We have developed FT-003 in-house based on our own intellectual property.

Drug Design and Mechanism of Action

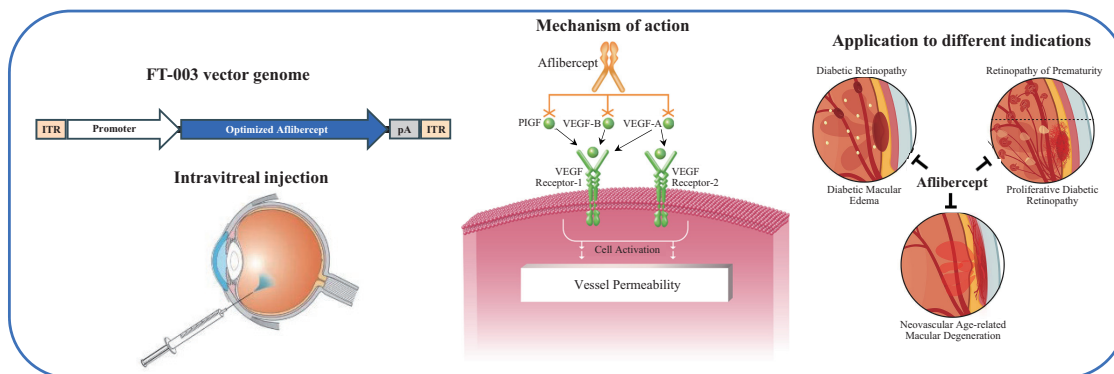
FT-003 utilizes an rAAV2m capsid that is administered via intravitreal injection. Unlike many other rAAV vectors, the rAAV2m capsid in FT-003 is specifically designed to efficiently penetrate the inner limiting membrane of the retina. This targeted vector design enables broad and deep transduction across multiple retinal cell layers.

The capsid carries a codon-optimized gene encoding aflibercept, a fusion protein comprising the extracellular domains of human VEGF receptors 1 and 2 (“**VEGFR1**” and “**VEGFR2**”) fused to the Fc portion of human IgG1. Upon administration, FT-003 enables the robust and sustained expression of aflibercept, which is driven by an optimized ubiquitous promoter and regulatory element.

Aflibercept acts as a soluble decoy receptor, binding with high affinity to vascular endothelial growth factor A and B (“**VEGF-A**” and “**VEGF-B**”), and placental growth factor (“**PlGF**”). By sequestering these pro-angiogenic factors, aflibercept effectively blocks their interaction with endogenous VEGF receptors on vascular endothelial cells. This inhibition disrupts the VEGF and PlGF signaling pathways, thereby suppressing pathological neovascularization, reducing vascular permeability, and preventing vascular leakage within the retina.

Through this mechanism, FT-003 addresses the underlying molecular drivers of nAMD and DME, providing a long-acting, one-time gene therapy solution that has the potential to significantly improve visual outcomes, reduce the need for frequent anti-VEGF injections, and alleviate the treatment burden for patients with these sight-threatening retinal diseases.

The following diagrams illustrate the vector genome and injection method of FT-003 on the left side, the mechanism of action of FT-003 in the middle, and the application of FT-003 to different indications on the right side:



Note: ITR = inverted terminal repeats; pA = polyadenylation signal.

Source: Literature Review

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Market Opportunities and Competition

nAMD and DME represent two of the leading causes of vision loss and blindness among the elderly worldwide. The prevalence of these conditions is rising in parallel with aging populations and increasing rates of diabetes, creating a substantial and growing patient pool in both China and international markets. There are approximately 4.2 million nAMD patients and 7.8 million DME patients in China and approximately 1.6 million nAMD patients and 2.0 million DME patients in the United States in 2025. Aside from these two countries, the rest of the world had approximately 15.8 million nAMD patients and 16.9 million DME patients in 2025.

Current standard-of-care therapies for nAMD and DME primarily rely on frequent intravitreal injections of anti-VEGF agents. These regimens impose a significant treatment burden on patients and healthcare systems due to the need for repeated injections — often as frequently as every four to eight weeks. The high frequency of administration not only increases direct medical costs but also leads to indirect costs, including patient and caregiver time, travel, and lost productivity. According to a published cost-effectiveness study in the UK, long-term anti-VEGF therapy is estimated to average a total of 9.2 quality-adjusted life years. On this base, the total treatment costs of anti-VEGF therapy are calculated to be up to US\$304,000 in the United States and up to RMB403,000 in China. This cumulative financial burden, combined with the inconvenience and discomfort of repeated injections, often results in suboptimal patient compliance and poor long-term outcomes.

There is a clear and urgent unmet need for long-acting therapies that can provide durable disease control with fewer interventions. Therapies that can reduce the frequency of injections or offer a one-time treatment solution are expected to deliver higher clinical and economic value, improve patient quality of life, and reduce the overall burden on healthcare systems.

The market potential for therapies in nAMD and DME is substantial. In China and the United States, the patient populations for nAMD and DME are forecasted to continue growing steadily. The global ophthalmic anti-VEGF drug market was US\$17.9 billion in 2025 and is expected to reach US\$41.8 billion in 2035, according to Frost & Sullivan. The positive market outlook is further supported by the increasing adoption of advanced therapies and the willingness of payers to support treatments that offer increased durability and reduced treatment burden.

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As of the Latest Practicable Date, there are 24 rAAV gene therapy drug candidates in clinical stage for the treatment of nAMD. FT-003 is the most advanced intravitreal gene therapy for nAMD in China in terms of clinical development progress. The following chart illustrates the global competitive landscape of FT-003 for nAMD as of the Latest Practicable Date, according to Frost & Sullivan:

Route of Administration	Drug Name	Company	Target	Vector Type	Phase	First Posted Date	Country	Manufacturing System
Intravitreal	Exobergene soroparvovect (Ixo-vec, ADVV-022)	Eli Lilly / Adverum	VEGF	AAV2.7m8	Phase III	2025/3/4	US	Bac/Sf9
	zunibergene rocpavovect (4D-150)	4D Molecular Therapeutics	VEGFA; VEGFB; VEGFC; PLGF	AAV vector R100	Phase III	2025/3/7	US, Canada	HEK293
	SKG0106	Skyline Therapeutics	VEGFA	AAV	Phase I/II	2023/8/14	China, US	NA
	FT-003	Frontera Therapeutics	VEGF	AAV	Phase II Phase II IND Approval	2024/9/26¹ 2024/11/11	China US	Bac/Sf9
	XMVA09	Starrygene Therapeutics Company Limited	ANGPT2, VEGF	AAV	Phase I/II	2024/4/12	China	NA
	ABI-110	Avirmax Biopharma	VEGF	AAV2.N54	Phase I/II	2024/8/12	US	Bac/Sf9
	GZ402663	Sanofi	VEGF	AAV2	Phase I/II	2024/10/28	US	NA
	IVB-103	Innovac Biotherapeutics	-	AAV	Phase I/II	2024/11/29	China	NA
	EXG202	Hangzhou Jiayin Biotechnology Co., Ltd	ANGPT2, VEGF	AAV	Phase I/II	2025/9/18	China	NA
Subretinal	LX111	Innostellar Biotherapeutics	VEGF	AAV	Phase I	2025/7/8	China	NA
	Surabgene lomparvovect (Sura-vec, ABBV-RGX-314)	Abbvie / Regeneron	AAV8-VEGF	AAV8	Phase III	2022/6/7	US, UK, Japan, etc.	HEK293
	LX102	Innostellar Biotherapeutics	VEGF	AAV	Phase III	2025/12/29	China	NA
	JWK001	Chengdu Gene Vector Biotechnology	VEGF	AAV	Phase II	2026/8/20	China	NA
	KH631	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	VEGF	AAV	Phase I/II	2023/1/5	China	NA
	EXG102-031	Hangzhou Jiayin Biotechnology Co., Ltd	ANGPT2, VEGFA, VEGFC	AAV	Phase I	2022/12/10	US	NA
	NG101	Reyon Pharmaceutical, NeuracleGenetics	VEGF	AAV	Phase I/II	2023/8/9	US, Canada	NA
	RRG001	Shanghai RefreshGene Therapeutics	VEGF	AAV	Phase I/II	2023/11/21	China	NA
	NGGT007	Next Generation Gene Therapeutics	CYP4V2	AAV	Phase I/II	2025/1/16	China	NA
	CRG-B191	Shanghai Keruik Pharmaceutical Technology	VEGF	AAV	Phase I/II	2025/11/6	China	NA
	HG202	Huida Gene Therapeutics Co., Ltd.	VEGF	AAV	Phase I	2023/9/4	China	NA
	RGL-2201	Shanghai Regenelead Therapies Co., Ltd.	VEGF	AAV	Phase I	2025/3/3	China	NA
Suprachoroidal	AL-001	Beijing Anlong Biopharmaceutical Co., Ltd	VEGF	AAV	Phase II	2025/2/17	China	Bac/Sf9
	KH658	Chengdu Kanghong Pharmaceutical Group	VEGF	AAV	Phase I/II	2024/6/13	China	NA

Note:

* “NA” indicates that the manufacturing system of the corresponding product has not been publicly disclosed.

(1) FT-003 has completed both Phase I and Phase II clinical trials. The first posted date disclosed herein refers to the date on which the first participant in the Phase II trial signed the informed consent form.

Source: Clinicaltrial.gov, CDE, Frost & Sullivan Report

The following chart illustrates the global competitive landscape of FT-003 for DME as of the Latest Practicable Date, according to Frost & Sullivan:

Route of Administration	Drug Name	Company	Target	Vector type	Phase	First Posted Date	Country	Manufacturing System
Intravitreal	zunibergene rocpavovect (4D-150)	4D Molecular Therapeutics	VEGFA, VEGFB, VEGFC, PLGF	AAV vector R100	Phase II	2023-07-05	US, Puerto Rico	HEK293
	FT-003	Frontera Therapeutics	VEGF	AAV	Phase II Phase II IND Approval	2024-10-22¹ 2024-12-25	China US	Bac/Sf9
	SKG0106	Skyline Therapeutics	VEGFA	AAV	Phase I	2024-02-01	China	NA
	LX111	Innostellar Biotherapeutics	VEGF	AAV	Phase I	2026-01-23	China	NA
	Surabgene lomparvovect (Sura-vec, ABBV-RGX-314)	Abbvie / Regeneron	VEGF	AAV8	Phase II/III	2026-05-18	US, Puerto Rico	HEK293
Suprachoroidal	KH658	Chengdu Kanghong Pharmaceutical Group	VEGF	AAV	Phase II	2026-07-07	China	NA

Note:

* “NA” indicates that the manufacturing system of the corresponding product has not been publicly disclosed.

(1) The first posted date disclosed herein refers to the date on which the first participant in the Phase II trial signed the informed consent form.

Source: Clinicaltrial.gov, CDE, Frost & Sullivan Report

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Key Advantages

FT-003 combines validated molecular targeting, vector and gene design, robust and durable clinical efficacy, a favorable safety profile, and industry-leading manufacturing efficiency.

- **Potential with Long-Term Disease Control, Significant Reduction in Treatment Burden, and Favorable Safety Profile.** Clinical data from Phase I and Phase II clinical trials demonstrate that FT-003 may have comparable efficacy and safety profile compared to notable competitors such as Ixo-vec and 4D-150 for nAMD (based on their latest publicly available trial results, not head-to-head comparisons).

nAMD

- o FT-003 has demonstrated sustained improvements in both BCVA and CST through 52 weeks after administration in the Phase II clinical trial, with the high-dose cohort demonstrating performance comparable to that of the aflibercept control group at Week 52. In the Phase II clinical trial, a single intravitreal injection of high-dose FT-003 resulted in a LS mean BCVA increase of 10.4 letters and a LS mean CST reduction of 73 μ m at Week 52, with 79% of participants not requiring any subsequent anti-VEGF injections and 89% receiving no more than one injection.
- o Our Phase II clinical trial indicated that FT-003 may have a comparable efficacy and safety profile compared to the latest publicly available clinical trial results of notable gene therapy competitors, such as Ixo-vec and 4D-150, based on a non-head-to-head comparison.

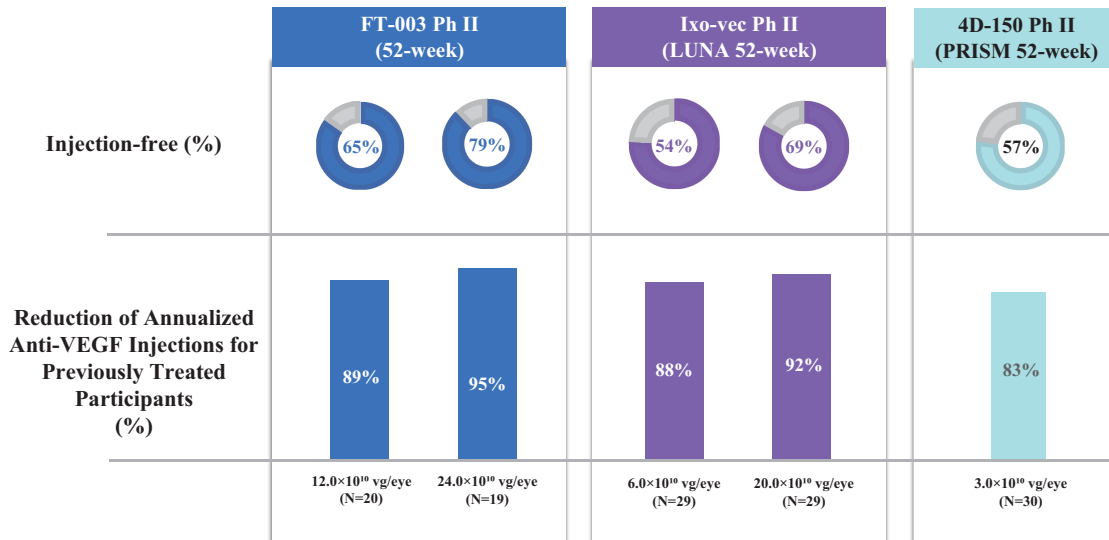
Product (Clinical phase)	FT-003 (Phase II at Week 52)	Ixo-vec (Phase II LUNA at Week 52)	4D-150 (Phase II PRISM at Week 52)
BCVA change from BL (ETDRS letters)	+6.2 (12.0×10^{10} vg/eye, N=20) +10.4 (24.0×10^{10} vg/eye, N=19)	+2.1 (6.0×10^{10} vg/eye, N=28) +1.8 (2.0×10^{11} vg/eye, N=29)	+2.2 (3.0×10^{10} vg/eye, N=30)
CST change from BL (μ m)	-81 (12.0×10^{10} vg/eye, N=20) -73 (24.0×10^{10} vg/eye, N=19)	-10.2 (6.0×10^{10} vg/eye, N=30) -21.9 (2.0×10^{11} vg/eye, N=30)	+11.0 (3.0×10^{10} vg/eye, N=30)

Note: The BCVA and CST data for FT-003 and Ixo-vec are presented as LS means, while those for 4D-150 are presented as mean $\pm$ standard deviation. The data for Ixo-vec and 4D-150 are presented in the metrics and formats publicly disclosed by the respective companies. Clinical data are not from head-to-head clinical trials, thus not directly comparable.

Source: Company Data, Literature Review

- o The annualized rate of anti-VEGF rescue injections also demonstrated significant reductions following FT-003 injection. The rate was reduced by 79% in the Phase I clinical trial, with 7 out of 11 participants (63.6%) requiring no additional injections during the entire year. As illustrated below, at Week 52 of the Phase II clinical trial, 65% and 79% of the low- and high-dose groups for FT-003 achieved injection-free status, which is comparable with peer products at similar times of their Phase II clinical trial. Reductions in injection frequency were 89% and 95% for the low- and high-dose groups for FT-003, compared with 88% and 92% for Ixo-vec and 83% for 4D-150.

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Note: Clinical data are not from head-to-head clinical trials, thus not directly comparable.

Source: Company Data, Literature Review

DME

- o The need for anti-VEGF therapy was reduced by 67% in the Phase I clinical trial, with two out of nine Phase I participants requiring no anti-VEGF therapy injections over 52 weeks after administration.
- o In the IIT study and Phase I clinical trial, FT-003 exhibited generally comparable efficacy to the performance of a notable gene therapy candidate, 4D-150, based on its latest publicly available clinical trial results. The following table sets forth a non-head-to-head comparison of FT003 and 4D-150.

Product (Clinical phase)	FT-003 (IIT & Phase I)	4D-150 (Phase II SPECTRA)
Mean BCVA change from baseline at Week 52 (ETDRS letters)	+2.7 (2.0 × 10 ¹⁰ vg/eye, N=3) +7.3 (24.0 × 10 ¹⁰ vg/eye, N=3) +11.7 (12.0 × 10 ¹⁰ vg/eye, N=3) +7.3 (24.0 × 10 ¹⁰ vg/eye, N=3)	+9.2 (5.0 × 10 ⁹ vg/eye & 1.0 × 10 ¹⁰ vg/eye, N=11) +6.4 (3.0 × 10 ¹⁰ vg/eye, N=9)
Mean CST change from baseline at Week 52 (μm)	-170 (2.0 × 10 ¹⁰ vg/eye, N=3) -225 (6.0 × 10 ¹⁰ vg/eye, N=3) -214 (12.0 × 10 ¹⁰ vg/eye, N=3) -192 (24.0 × 10 ¹⁰ vg/eye, N=3)	-140 (5.0 × 10 ⁹ vg/eye & 1.0 × 10 ¹⁰ vg/eye, N=11) -131 (3.0 × 10 ¹⁰ vg/eye, N=9)

Note: Clinical data are not from head-to-head clinical trials, thus not directly comparable.

Source: Company Data, Literature Review

- **One-Time, Long-Acting Therapy with Attractive Commercial and Patient Value Proposition:** By offering a single-administration, long-acting solution, FT-003 has the potential to transform the standard of care for nAMD and DME, improving patient quality of life and reducing the overall burden on healthcare systems. In addition, FT-003 is produced using our AAVANCE™ manufacturing platform, which enables large-scale, GMP-compliant production with high yields, low empty capsid rates, and a highly competitive production cost.
- **Convenient and Widely Adopted Administration.** FT-003 is administered via a single intravitreal injection, a minimally invasive procedure that can be performed quickly and safely in a standard outpatient setting without the need for specialized surgical equipment or highly technical expertise. This ease of administration supports broad clinical adoption and enhances patient access, distinguishing intravitreal injection from other delivery methods such as subretinal and suprachoroidal injections. For a comparison of the major injection methods, see “Industry Overview.”

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- **Fully Validated Target and Optimized Gene Design.** FT-003 encodes aflibercept, a well-established anti-VEGF fusion protein, ensuring a high probability of clinical success by targeting a validated molecular pathway in retinal vascular diseases. The engineered rAAV2m capsid enables efficient transduction of retinal cells via intravitreal injection, while codon optimization and regulatory element refinement ensure robust and sustained aflibercept expression.

Summary of Clinical Trial Data for nAMD

Investigator Initiated Trial

We worked with Prof. Xiaorong Li at the Tianjin Medical University Eye Hospital for the investigator-initiated trial of FT-003 for nAMD. We collaborated with the hospital as it had applicable clinical research qualifications, leading experts in the field, and access to a large patient pool.

Based on the terms of our collaboration agreement, we are responsible for designing the trial protocol upon consultation with the investigator, supplying the drugs required and bearing all expenses associated with the investigator-initiated trial, which were funded by our working capital. During the Track Record Period, we incurred a total of US\$0.2 million in professional services expenses associated with the trial and expect to incur an additional US\$0.1 million. The investigator was primarily responsible for executing the trial plan. We have exclusive rights and ownership over all clinical trial data, IPs, know-hows, technologies, and other material aspects over FT-003 with respect to nAMD arising from the investigator-initiated trial. The investigator has not filed any patent applications relating to FT-003 with respect to nAMD. There is no explicit confidentiality provision in our collaboration agreement.

We did not rely on the results of the investigator-initiated trial for obtaining the IND approval for FT-003 for nAMD from NMPA, since the investigator-initiated trial was concluded in May 2025 and we, as the sole sponsor, submitted the IND application for FT-003 for nAMD, which did not reference any data from the investigator-initiated trial, in February 2023 and obtained approval in April 2023. We solely own all patent applications in connection with FT-003 for nAMD filed by us, and have not out-licensed such pending patents to a third party. We are of the view that there are no valid third party patents enforceable against us in connection with FT-003 for nAMD. Thus, we have full and independent rights to conduct R&D and commercialization of FT-003 for nAMD.

Trial design. The investigator initiated trial of FT-003 was an open-label, dose-escalation trial in participants with nAMD. Two dose groups were set up: (i) low dose group (6.0×10^{10} vg/eye), which enrolled three participants; and (ii) medium dose group (12.0×10^{10} vg/eye) which enrolled one participant. Each participant received a single intravitreal injection of FT-003 at a volume of 50 μ L.

Trial objectives. The primary objective was to evaluate the safety, tolerability, and preliminary efficacy of FT-003 administered via intravitreal injection in participants with nAMD.

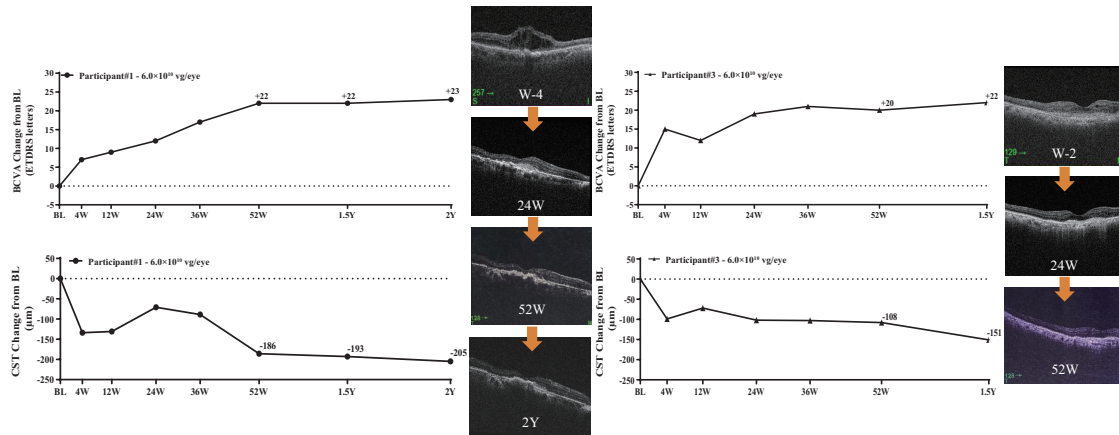
Trial status. The IIT study was initiated in December 2022 and completed its two-year follow-up in May 2025. All participants are undergoing five years of long-term follow-up.

Efficacy data. The efficacy results indicated FT-003 may offer sustained visual and anatomical benefits while reducing treatment burden in nAMD patients. A single intravitreal injection of FT-003 in four participants with nAMD resulted in improvements in BCVA and reductions in CST over a three years follow-up period.

Notably, in the low-dose group, two participants who received FT-003 maintained stable and improved BCVA over three years of follow-up, with retinal structure remaining normal as assessed by OCT imaging. Importantly, these participants did not require any additional anti-VEGF therapy during the observation period, and aflibercept was still

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detectable in the aqueous humor at the end of follow-up. This suggests that FT-003 effectively transduced retinal cells and enabled sustained, stable expression of aflibercept, providing ongoing therapeutic benefit and disease control for nAMD patients.



Source: Company Data

Safety data. The clinical results indicated that the overall tolerability and safety profile of FT-003 were favorable. No DLTs or SAEs related to FT-003 were observed. The only adverse events reported were intraocular inflammatory reactions commonly associated with rAAV gene therapy products and intravitreal injections. No new or unexpected safety risks were identified during the study period.

Phase I Clinical Trial

Trial design. The dose escalation Phase I clinical trial was an open-label, multicenter, and non-randomized study. The trial enrolled a total of 11 participants, with each participant receiving a single intravitreal injection of FT-003 in one eye. Three dose cohorts were established: (i) low dose group: 6.0×10^{10} vg/eye, which enrolled three participants; (ii) medium dose group: 12.0×10^{10} vg/eye, which enrolled four participants; and (iii) high dose group: 24.0×10^{10} vg/eye, which enrolled four participants.

Key inclusion criteria for the trial include but are not limited to (i) male and female participants aged 50 to 80 years old, (ii) clinically diagnosed with nAMD, (iii) BCVA of no lower than 24 letters and no more than 73 letters for the study eye, and BCVA of no lower than 19 letters for the fellow eye, (iv) received anti-VEGF treatment in the previous six months prior to screening, and (v) has demonstrated a clinical response to anti-VEGF treatment prior to enrollment. Key exclusions criteria for the trial include but are not limited to (i) choroidal neovascularization due to causes other than AMD in the study eye, (ii) had relevant treatment record and/or allergies, including recent eye surgeries, other gene therapy treatment, or allergies to materials used in the trial, (iii) has systemic risks such as stroke, and (iv) anti-AAV2m neutralizing antibody titer is larger than 1:1,000.

After receiving FT-003, all participants completed 12 weeks of observation, and, according to the requirement and authorization of the CDE-approved trial protocol, an iDMC meeting, comprising of a group of independent experts, was held to review the safety and tolerability data of all participants and confirm the initiation of the Phase II dose-expansion study. Meanwhile, all participants were expected to complete 52 weeks of follow-up. Participants who completed the Week 52 visit or withdrew early entered the long-term follow-up period until five years after injection.

Trial objectives. The primary objectives were to evaluate the safety, tolerability and efficacy of a single intravitreal injection of FT-003 in nAMD patients. Primary endpoints relate to safety and tolerability within 12 weeks of injection, and include DLT within 28 days and incidents of AEs and SAEs. Secondary endpoints relate to safety and tolerability within

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52 weeks of injection, efficacy within 12 and 52 weeks of injection, including changes in BCVA from baseline, immunogenicity and AAV shedding.

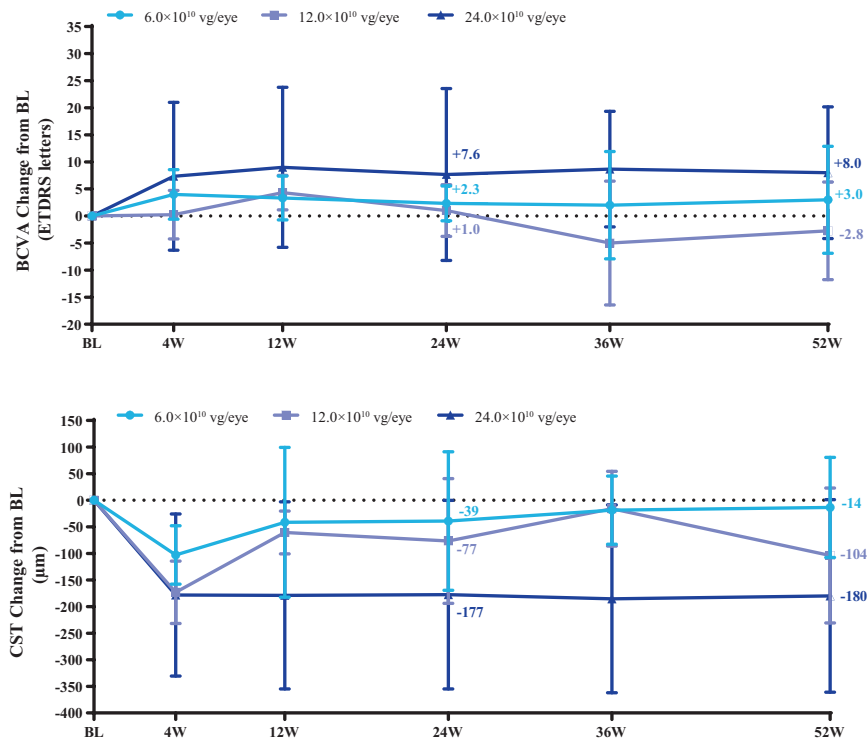
Trial status. The clinical trial was initiated in August 2023, and completed in August 2024. The primary endpoints, which are 12-week safety and tolerability data and the only prerequisites for the initiation of Phase II clinical trials, were evaluated by the iDMC which confirmed the initiation of Phase II in August 2024. No communication with the CDE is required to confirm whether the primary or secondary endpoints were met until we propose to initiate the Phase III clinical trials. Secondary endpoints, which are safety, efficacy, immunogenicity and AAV shedding data within 52 weeks post FT-003 injection, were assessed in September 2025 and have met our trial objectives. All participants are undergoing five years of long-term follow-up.

Efficacy data. The clinical data illustrate that FT-003 has the potential to deliver long-lasting clinical benefits for nAMD patients, including meaningful gains in visual acuity, anatomical improvements in the retina, and a dramatic reduction in the burden of ongoing anti-VEGF therapy. Following FT-003’s injection, therapeutic levels of aflibercept were detectable in aqueous humor for up to 52 weeks in all three dose groups, indicating sustained aflibercept expression mediated pharmacological effect.

Particularly, the high dose group exhibited the most pronounced efficacy. At Week 52, participants in this group achieved a mean BCVA improvement of 8 letters and a mean CST reduction of 180 μm , with 33% of participants achieving a BCVA improvement of more than 15 letters. BCVA measures the participant’s visual functions, and CST, or central subfield thickness, is an objective, quantifiable measure of retinal thickness in the central part of the macula, providing biological evidence on participants’ retinal structure. Both parameters are internationally recognized parameters used for the evaluation of product candidates for the treatment of nAMD and DME in the world. Improvements in BCVA of no less than 5 letters is deemed the minimal clinically important difference, and improvements of no less than 15 letters is deemed to significantly improve vision. The high dose group’s improvements in BCVA, especially sustained over 52 weeks, indicate ability to restore or preserve central vision. Meanwhile, a reduction in CST of no less than 50 μm is deemed clinically meaningful. The high dose group’s 180 μm reductions in CST reflect FT-003’s ability to restore retinal structure. These results indicate that FT-003 can provide sustained improvements in both visual function and retinal structure.

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The following diagram sets forth changes in BCVA and CST from baseline for each of the dosage cohort up to 52 weeks after injection. The low dose and medium dose groups generally had less significant improvements in BCVA and CST.



Source: Company Data

No comparison against the fellow eye was done since the fellow eye may not be diagnosed with nAMD, and even in cases of nAMD, the medical and treatment history and the baseline characteristics (e.g. BCVA and CST) may be different with the study eye. In addition, we did not restrict treatment of the fellow eye during the study.

Among all the participants, the annualized anti-VEGF injection rate was reduced by 79%. Annualized anti-VEGF injection rate is also an internationally recognized parameter for the evaluation of similar gene therapy products in the world, and is calculated as the percentage difference between the number of pre- and post-treatment annualized anti-VEGF injection. Notably, among the three high-dose participants who have completed 52-week follow-up, none required any anti-VEGF rescue injections during the entire year, representing a decrease in annualized anti-VEGF injection rate of 100%. For the low and medium-dose groups, annualized anti-VEGF injection rate decreased by 32% and 75%, respectively. The results indicate a substantial decrease in the need for additional anti-VEGF therapy and, consequently, a potential improvement in patient compliance and quality of life. However, no marked and consistent reduction of CNV area and leakage area were measured among the three dose groups at Week 52.

Safety data. FT-003 demonstrated a favorable safety profile and was well-tolerated across all tested dose levels in participants up to 1 year follow-up. All participants received only light steroid prophylaxis, and the overall tolerability was excellent. Trace to mild intraocular inflammation was observed in a few participants, all of which were effectively managed and controlled with standard steroid treatment, and did not result in any serious complications. No DLTs or SAEs related to FT-003 were reported throughout the study. Aside from the above-mentioned ocular inflammatory events, no new or unexpected safety risks were identified. Although humoral immune responses against AAV (neutralizing antibody) were detected in 2 participants in the low-dose group, no specific cellular immune responses

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were observed in any participants, and therefore no correlation between the safety of FT-003 and immune responses has been identified to date. Furthermore, during long-term follow-up, no participants experienced FT-003-related decreases in intraocular pressure, and no other significant ocular or systemic safety issues were observed. No Grade 3 or above AEs were observed throughout the study. There was no adverse event that led to patient withdrawal or study discontinuation.

With respect to AAV shedding, transient and low levels of FT-003 vector genomic DNA were detected in the peripheral blood, urine and tears from both eyes of 11 participants, while no significant or sustained AAV shedding was observed.

Phase II Clinical Trial

Trial design. The dose expansion Phase II clinical trial was a randomized, aflibercept positive control, single-blind, multicenter study. Based on safety and efficacy data from participants for at least 12 weeks in the Phase I clinical trial, the iDMC recommended doses of 12.0×10^{10} vg/eye and 24.0×10^{10} vg/eye of FT-003 for initiating the Phase II study. Therefore, three cohorts were established in a 1:1:1 ratio: (i) low dose group: 12.0×10^{10} vg/eye; (ii) high dose group: 24.0×10^{10} vg/eye; and (iii) aflibercept group: 2 mg Q8W. A total of 62 participants has been enrolled into these three groups, with low dose, high dose and aflibercept groups comprising 20, 19 and 22 participants, respectively.

Except for enrolling both naive and pre-treated participants, key inclusion and exclusion criteria for the trial are the same as the inclusion and exclusion criteria for the Phase I clinical trial.

After receiving FT-003, all participants completed 52 weeks of follow-up to assess its safety, efficacy, pharmacokinetics and immunogenicity. Participants have entered long term follow-ups up to 5 years after completing the Week-52 visit or withdrawing early.

Trial objectives. The primary objective of this Phase II clinical trial was to evaluate the efficacy and safety of FT-003 in improving visual function BCVA as measured by the change from baseline following a single intravitreal injection in nAMD patients. Primary endpoints relate to efficacy within 24 weeks of injection, and include changes in BCVA from baseline. Secondary endpoints relate to efficacy (e.g. changes in BCVA and CST from baseline) and safety (e.g. incidents of AEs and SAEs), immunogenicity and AAV shedding within 52 weeks of injection.

Trial status. This Phase II clinical trial was initiated in October 2024, and completed the participants enrollment in July 2025. In July 2026, the Phase II clinical trial was completed as, except for one participant who was not administered the drug due to withdrawal of informed consent, all participants have completed 52 weeks of follow-up based on recommendations of the CDE (for details of our communication with the CDE, please see “— Material Communications and Next Steps”). All endpoints have been assessed and are expected to be submitted to the CDE for evaluation in the third quarter of 2026. We expect to obtain a no-objection confirmation from the CDE in the fourth quarter of 2026 and initiate Phase III clinical trial by the first quarter of 2027.

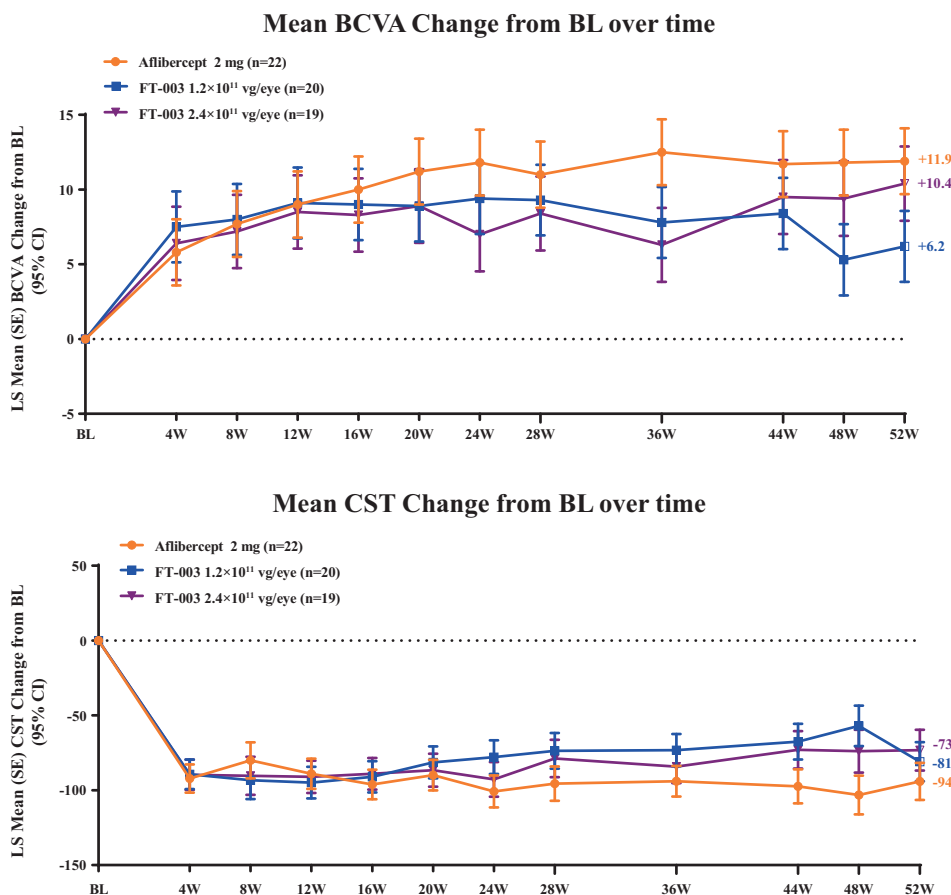
Efficacy data. Available clinical data from the completed 52-week follow-up demonstrate that FT-003 has the potential to deliver sustained and clinically meaningful benefits for nAMD patients, including meaningful gains in visual acuity, anatomical improvements in the retina, and a dramatic reduction in the burden of ongoing anti-VEGF therapy.

At Week 52, the least squares mean changes (LS Mean, 95%CI) from baseline in BCVA of the low-dose and high-dose groups were 6.2 and 10.4 letters, and the LS Mean from baseline in BCVA of the aflibercept control group was 11.9 letters. The differences between the treatment groups and control group are statistically insignificant, with p-values of 0.0815 and 0.6641, respectively. Notably, the high-dose cohort exceeded the aflibercept control group at Week 52, with 38.9% of participants achieving BCVA gains of 15 letters or more, compared

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to 31.8% in the aflibercept group. In addition, the low-dose and high-dose cohorts saw mean reductions in CST from baseline, with LS Mean of -81 μm and -73 μm , respectively, whereas the aflibercept control group saw reductions from baseline of -94 μm . The differences between the treatment groups and control group are statistically insignificant, with p-values of 0.4687 and 0.2607, respectively.

The following diagram sets forth changes in BCVA and CST from baseline for each of the dosage cohort up to 52 weeks after injection.



Source: Company Data

In terms of the need for ongoing anti-VEGF therapy at week 52, 65% and 79% of the participants in the low-dose and high-dose cohorts, respectively, did not receive any subsequent aflibercept treatment, and 80% and 89% received no more than one injection. The mean cumulative number of aflibercept injections was 0.32 and 0.65 for the low-dose and high-dose cohorts, respectively, compared to 6.0 for the aflibercept control group, representing reductions of approximately 95% and 89%, respectively.

Safety data. Available clinical data have demonstrated a favorable safety and tolerability profile of FT-003 for nAMD. To date, there were no TEAEs leading to death or trial discontinuation, no suspected unexpected serious adverse reactions, no SAEs related to FT-003, and no new AAV-related safety risk signals.

With respect to AAV shedding, vector genomic DNA was tested negative in peripheral blood at Week-4 and in tears from both eyes in Week-24, indicating that FT-003 is primarily distributed in ocular tissues with limited systemic exposure and potential environmental shedding following intravitreal injection. No significant or sustained AAV shedding was observed.

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Summary of Clinical Trial Data for DME

Investigator Initiated Trial

We worked with Prof. Xiaorong Li at the Tianjin Medical University Eye Hospital for the investigator-initiated trial of FT-003 for DME. We collaborated with the hospital as it had applicable clinical research qualifications, leading experts in the field, and access to a large patient pool.

Based on the terms of our collaboration agreement, we are responsible for designing the trial protocol upon consultation with the investigator, supplying the drugs required and bearing all expenses associated with the investigator-initiated trial, which were funded by our working capital. During the Track Record Period, we incurred a total of US\$0.2 million in professional services expenses associated with the trial and expect to incur an additional US\$0.1 million. The investigator was primarily responsible for executing the trial plan. We have exclusive rights and ownership over all clinical trial data, IPs, know-hows, technologies, and other material aspects over FT-003 with respect to DME arising from the investigator-initiated trial. The investigator has not filed any patent applications relating to FT-003 with respect to DME. There is no explicit confidentiality provision in our collaboration agreement.

We did not rely on the results of the investigator-initiated trial for obtaining the IND approval for FT-003 for DME from NMPA, since the investigator-initiated trial was concluded in July 2025 and we, as the sole sponsor, submitted the IND application for FT-003 for DME, which did not reference any data from the investigator-initiated trial, in May 2023 and obtained approval in August 2023. We solely own all patent applications in connection with FT-003 for DME filed by us, and have not out-licensed such pending patents to a third party. We are of the view that there are no valid third party patents enforceable against us in connection with FT-003 for DME. Thus, we believe we have full and independent rights to conduct R&D and commercialization of FT-003 for DME.

Trial design. The investigator initiated trial was initially designed as an open-label, dose-escalation study in participants with DME. The trial enrolled a total of 3 participants who received 2.0×10^{10} vg/eye in a single intravitreal injection of FT-003 at a volume of 50 μ L.

Trial objectives. The primary objective was to evaluate the safety and tolerability of FT-003.

Trial status. The IIT study was initiated in May 2023 and completed its two-year follow-up in July 2025. All participants are undergoing five years of long-term follow-up.

Efficacy data. The preliminary efficacy results indicated FT-003 may offer sustained visual and anatomical benefits. A single intravitreal injection of FT-003 in three DME participants resulted in improvements in BCVA and reductions in CST over two years.

Importantly, the average annualized rate of anti-VEGF injections among these participants decreased by 86% compared to the pre-treatment period, demonstrating that FT-003 may substantially reduce the need for additional anti-VEGF interventions in most treated participants.

Safety data. Overall, FT-003 demonstrated a favorable safety profile in this cohort, with no DLTs, no treatment-related SAEs, and no intraocular inflammation observed.

Phase I Clinical Trial

Trial design. The dose escalation Phase I clinical trial was an open-label, multicenter, study. The trial enrolled a total of nine participants, with each participant receiving a single intravitreal injection of FT-003 in one eye. Three dose cohorts are established: (i) low dose group: 6.0×10^{10} vg/eye; (ii) medium dose group: 12.0×10^{10} vg/eye; and (iii) high dose group: 24.0×10^{10} vg/eye. A total of nine participants has been enrolled and randomly assigned in a 1:1:1 ratio into these three groups, with each group comprising three participants.

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Key inclusion criteria for the trial include but are not limited to (i) male and female participants aged 18 to 74 years old, (ii) clinically diagnosed with DME for the study eye, (iii) BCVA of no lower than 24 letters and no more than 73 letters for the study eye, and BCVA of no lower than 19 letters for the fellow eye, and (iv) has demonstrated a clinical response to anti-VEGF treatment in the study eye prior to enrollment. Key exclusions criteria for the trial include but are not limited to (i) diabetic retinopathy severity scale of no lower than 65 before enrollment, (ii) study eye has ophthalmic diseases other than DME, (iii) had relevant treatment record and/or allergies, including recent eye surgeries, other gene therapy treatment, or allergies to materials used in the trial, and (iv) anti-AAV2m neutralizing antibody titer is greater than 1:640.

After receiving FT-003, all participants completed 12 weeks of observation, and, according to the requirement and authorization of the CDE-approved trial protocol, an iDMC meeting, comprising of a group of independent experts, was hold to review the safety and tolerability data of all participants and confirm the initiation of the Phase II dose-expansion study. Meanwhile, all participants were expected to complete 52 weeks of follow-up. Participants who completed the Week 52 visit or withdrew early entered the long-term follow-up period until 5 years after FT-003 injection.

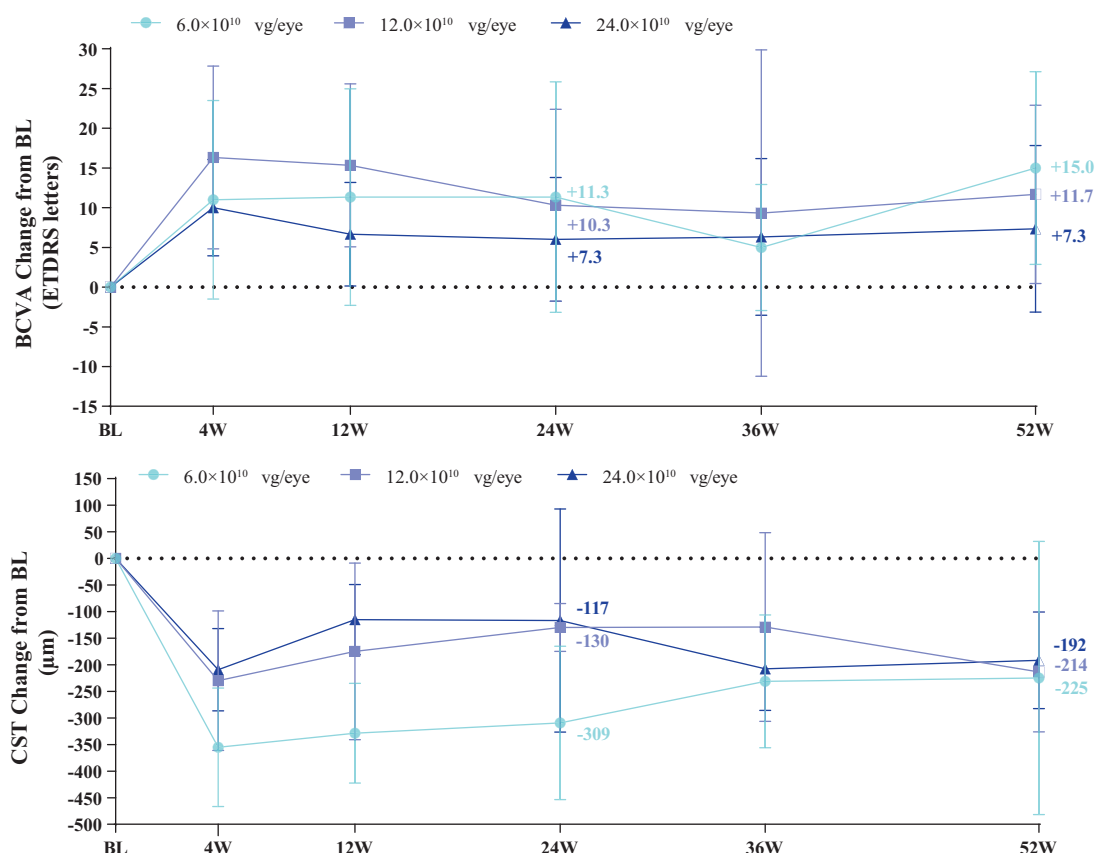
Trial objectives. Primary endpoints relate to safety and tolerability within 12 weeks and 52 weeks of injection, and include DLT within 28 days and incidents of AEs and SAEs. Secondary endpoints relate to efficacy within 12 and 52 weeks of injection, including changes in BCVA from baseline, immunogenicity and AAV shedding.

Trial status. The Phase I clinical trial was initiated in December 2023 and completed in October 2024. The iDMC meeting then evaluated the primary endpoints, which are the only prerequisites for the initiation of Phase II clinical trials, and confirmed this initiation. No communication with the CDE is required to confirm whether the primary or secondary endpoints were met until we propose to initiate the Phase III clinical trials. Furthermore, 52-week follow-up was completed in September 2025, in which the results have met our trial objectives regarding secondary endpoints. All participants are undergoing five years of long-term follow-up.

Efficacy data. The clinical data illustrated that FT-003 has the potential to deliver long-lasting clinical benefits for DME patients, including meaningful gains in visual acuity, anatomical improvements in the retina, and a dramatic reduction in the burden of ongoing anti-VEGF therapy.

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In particular, compared with baseline, the mean BCVA increased by 11 letters, with 44.4% of participants achieving BCVA gain of more than 15 letters, and the mean CST decreased by 210 μm across three dose groups at Week 52. The following diagram illustrates changes in BCVA and CST among the three cohort groups up to 52 weeks after injection.



Source: Company data

No comparison against the fellow eye was done since the fellow eye may not be diagnosed with DME, and even in cases of DME, the medical and treatment history and the baseline characteristics (e.g. BCVA and CST) may be different with the study eye. In addition, we did not restrict treatment of the fellow eye during the study.

Importantly, the treatment burden was substantially alleviated, with a 76% reduction in the frequency of anti-VEGF injections at Week 52 post-administration, compared to the projected number of on-label aflibercept 2 mg Q8W injections.

Safety data. FT-003 has demonstrated a favorable safety profile and was well-tolerated across all tested dose levels in participants with DME, with the longest follow-up extending to 2 years. All participants received only light steroid prophylaxis, and the overall tolerability of FT-003 was excellent. Trace to mild intraocular inflammation was observed in some participants; however, these events were effectively managed and controlled with standard steroid treatment. Importantly, no DLTs or SAEs related to FT-003 were reported throughout the study period. The safety events observed were consistent with those commonly associated with rAAV gene therapy products and intravitreal injection procedures, such as mild intraocular inflammation, and no new or unexpected safety risks were identified. No Grade 3 or above AEs were observed throughout the study. There was no adverse event that led to patient withdrawal or study discontinuation.

These results support the continued clinical development of FT-003 as a promising therapeutic option for patients with DME.

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With respect to AAV shedding, transient and low levels of FT-003 vector genomic DNA were detected in the peripheral blood, urine, tears from both eyes and/or nasal secretions of all participants, while no significant or sustained AAV shedding was observed.

Ongoing Phase II Clinical Trial

Trial design. The dose expansion Phase II clinical trial is a randomized, single-blind, multicenter study. Three dose cohorts are established in a 1:1:1 ratio: (i) low dose group: 6.0×10^{10} vg/eye; (ii) medium dose group: 12.0×10^{10} vg/eye; and (iii) high dose group: 24.0×10^{10} vg/eye. A total of 60 participants have been enrolled as of the Latest Practicable Date.

Key inclusion and exclusion criteria for the trial are the same as the inclusion and exclusion criteria for the Phase I clinical trial.

After receiving FT-003, all participants are expected to complete 52 weeks of follow-up to assess its safety, efficacy, pharmacokinetics and immunogenicity. Participants will also enter the long term follow-ups up to 5 years after completing the Week-52 visit or withdrawing early.

Trial objectives. Primary endpoint is related to efficacy within 24 weeks of injection, including changes in BCVA from baseline. Secondary endpoints are related to efficacy (e.g. changes in BCVA and CST from baseline), safety (e.g. incidents of AEs and SAEs), immunogenicity and AAV shedding within 52 weeks of injection.

Trial status. This Phase II clinical trial was initiated in November 2024, and enrollment of the last participant was completed in January 2026. As we have engaged in communications with the CDE with respect to FT-003 for nAMD, where the CDE recommended completing 52 weeks of follow-up before evaluating the initiation of the Phase III trial, we intend to voluntarily follow the same approach with FT-003 for DME. That is, we expect to submit an end-of-Phase II meeting request to discuss Phase III plans with the CDE after 52 weeks of follow-up are completed. We expect to obtain a no-objection confirmation from the CDE in the first quarter of 2027 and initiate Phase III clinical trial in the third quarter of 2027.

Material Communications and Next Steps

We received IND approval of nAMD from the NMPA in April 2023, which covered both a dose escalation Phase I and a dose expansion Phase II clinical trial as two distinct segments. We did not receive comments from the NMPA to our clinical trial plans before receiving the IND approval. Pursuant to the IND approval, we initiated and completed the Phase I clinical trial in August 2023 and August 2024 according to the trial design, and initiated the Phase II clinical trial in October 2024.

We received IND approval of DME from the NMPA in August 2023, which covered both a dose escalation Phase I and a dose expansion Phase II clinical trial as two distinct segments. We did not receive comments from the NMPA to our clinical trial plans before receiving the IND approval. Pursuant to the IND approval, we initiated and completed the Phase I clinical trial in December 2023 and October 2024 according to the trial design, and initiated the Phase II clinical trial in November 2024.

Taking into account the industry practice as advised by Frost & Sullivan, the dose escalation Phase I clinical trials for both nAMD and DME constituted a completed clinical trial with its main purpose aligning with the overall purpose of a conventional Phase I clinical trial, which is typically to assess safety and determine the dosage for Phase II clinical trial. Based on the provisions set forth in the Announcement for Drug Approval and FT-003 clinical trial protocols submitted to the CDE, our PRC Legal Advisor is of the view that we are not required to obtain additional regulatory approval from the NMPA for commencing the dose expansion Phase II clinical trials for both nAMD and DME in China. In December 2025, we consulted the Yangtze River Delta Center of the CDE (國家藥品監督管理局藥品審評檢查長三角分中心) regarding the commencement of our Phase II clinical trial after completion of the Phase I clinical trial. We reached a representative of the Yangtze River Delta Center from

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their official consultation hotline, which, as confirmed by our PRC Legal Adviser, (i) is an official channel for consultation with CDE on the matters regarding drug evaluation, including the application for drug clinical trials, and (ii) as such hotline is the official channel for consultation with the CDE, the representative who received the call is the qualified person to respond to public inquiries. According to Frost & Sullivan, it is also customary for companies in China to seek the CDE’s official views through the CDE’s official consultation hotline. We informed the representative of details of our clinical trials including the fact that our IND covered both a Phase I and a Phase II clinical trial and that the clinical trials do not have components outside of China. Based on our explanations, the representative confirmed that we are not required to obtain additional regulatory approval from the NMPA for commencing the Phase II clinical trial in China and expressed no objection for us to commence the Phase II clinical trials of FT-003.

In November and December 2024, the FDA approved Phase II clinical trials of FT-003 for nAMD and DME, respectively, in the United States. Our application materials for the Phase II clinical trial included CMC, preclinical, and Phase I clinical data generated in China, as well as proposed Phase II clinical trial plans in the U.S.. Before granting its IND approval, the FDA raised comments primarily regarding (i) for nAMD, languages in the informed consent, classification of adverse events, participant inclusion criteria, and compliance with GCP, and (ii) for DME, languages in the informed consent. We made corresponding changes to the Phase II trial plans accordingly. The FDA’s approvals for the Phase II clinical trial despite the absence of completed Phase I clinical trials in the United States were based on CMC, preclinical, and Phase I clinical data generated in China. The scope of the IND approval from the FDA covered (i) the Phase II study to evaluate the efficacy, safety and tolerability of a single intravitreal injection of FT-003 in participants with nAMD, and (ii) the Phase II study to evaluate the efficacy, safety and tolerability of a single intravitreal injection of FT-003 in participants with DME. Following FDA IND clearance for FT-003 for nAMD and DME, we do not currently plan to conduct Phase II clinical trials for nAMD and DME in the United States. Instead, we currently plan to complete the ongoing Phase II clinical trials for FT-003 for nAMD and DME in China and use the clinical data from the China studies to support our interactions with the FDA and our applications to proceed to Phase III clinical trials in the United States.

Additionally, in March 2025, we received the IND approval for the Phase II clinical trial of FT-003 for the treatment of DR from the NMPA. We directly applied for and received approval for Phase II clinical trials of FT-003 for DR, without having conducted Phase I clinical trials, because DME is the main cause of vision loss in DR patients and we had completed Phase I clinical trials of FT-003 for DME by then. Notwithstanding such approval, we do not currently plan to commence a Phase II clinical trial of FT-003 for DR in China. Based on the registration experience for anti-VEGF therapies for DR, we believe that it would be more efficient to complete the Phase III clinical trial of FT-003 for DME first and then submit a supplemental application for the Phase III clinical trial of FT-003 for DR.

To date, the NMPA and the FDA have not raised any objections or material concerns with respect to the development of FT-003. Based on the CDE-approved trial protocols of FT-003 for nAMD, after 24 weeks of follow-up have been completed and primary endpoints became available, we made a submission to the CDE to discuss Phase III clinical trial plans which included our then available Phase II clinical trial results. In July 2026, we received feedback that recommended completing 52 weeks of follow-up before evaluating the initiation of the Phase III trial. Following such recommendations, we have completed 52 weeks of follow-up for all participants. All endpoints have been assessed and the results are expected to be submitted to the CDE for evaluation in the third quarter of 2026. Save for the communications discussed above we have not received any comments from the CDE in relation to the clinical trial results of FT-003.

We are advancing FT-003 for both nAMD and DME indications. We anticipate initiating the Phase III clinical trial for nAMD in China by the first quarter of 2027 and initiating the Phase III clinical trial for DME in China by the third quarter of 2027.

We also expect to progress the clinical development of FT-003 in the United States at appropriate times. We intend to pursue further clinical development in the U.S. leveraging

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clinical data from China and in collaboration with local CROs. We submitted a Type C meeting request to the FDA on July 6, 2026 to discuss the Phase III clinical development plan and proposed regulatory approval pathway in the United States, and intend to seek a pre-Phase III meeting by the first quarter of 2027. In July 2026, FT-003 has been granted regenerative medicine advanced therapy (RMAT) designation by the FDA for the treatment of nAMD. We intend to submit an application for the FDA’s RMAT designation for FT-003 with respect to DME in the fourth quarter of 2026 and intend to seek a pre-Phase III meeting by the second quarter of 2027. Subject to applicable regulatory approvals, we intend to commence Phase III clinical trial of FT-003 for nAMD and DME in the United States by the end of 2027. We believe we have sufficient R&D capability in the U.S. to progress the clinical development of FT-003 through collaboration with local CROs. The amount of resources we dedicate to such development and the related timeline will depend on our management’s judgment of the latest regulatory and market conditions, the competitive landscape, and our internal readiness. We may consider collaborating with local partners for the commercialization of FT-003 in the United States.

FT-003 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

FT-001, a rAAV gene therapy for RPE65-related IRD, our Key Product

Overview

FT-001 is a gene therapy drug candidate for the treatment of IRD caused by biallelic mutations in the RPE65 gene, including Leber congenital amaurosis Type 2 (“LCA2”) and RP. These conditions are generally characterized by a progressive and irreversible decline in vision that results in blindness. Currently, treatment options remain severely limited. Luxturna[®] is the only gene therapy treatment option for RPE65-related IRD approved in the United States and Europe, and no gene therapy option has been approved in China.

FT-001 is our drug candidate at the most advanced stage of clinical development, and its robust clinical results provided early validation for our technology platforms. FT-001 received the Breakthrough Therapy designation from the CDE of the NMPA in June 2025. We have completed Phase I/II clinical trials in China in February 2025 and our Phase III clinical trial plan has been approved by the CDE of the NMPA in September 2025.

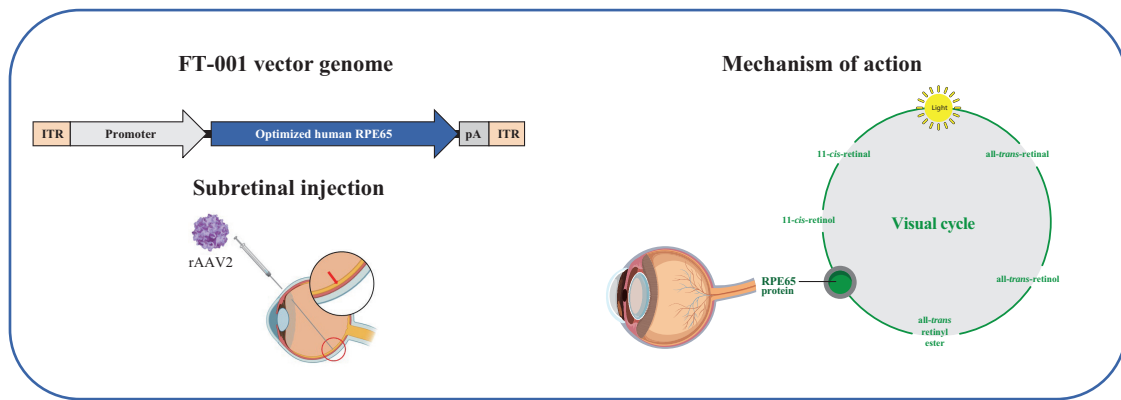
Drug Design and Mechanism of Action

Visual perception results from the biological conversion of light energy to electrical signaling by retinal photoreceptors in the eye. This biochemical process requires the consumption and regeneration of 11-cis-retinal, a derivative of Vitamin A, as a part of the visual cycle. One of the enzymes involved in the regeneration of 11-cis-retinal is an all-trans-retinyl isomerase, a 65 kDa protein expressed in the retinal pigment epithelium (the “RPE65 protein”). Biallelic mutations in the RPE65 gene encoding such RPE65 proteins impair the regeneration of 11-cis-retinal, and ultimately lead to the progressive degeneration of photoreceptors and loss of vision.

The therapeutic strategy of FT-001 centers on introducing a functional, codon-optimized human RPE65 gene into the retinal pigment epithelium. This is achieved using an rAAV vector with efficient cellular transduction for sustained gene expression. The genetic payload is packaged within an optimized expression cassette to ensure high-level and durable production of the functional RPE65 protein, which facilitates the regeneration of 11-cis-retinal that are necessary for both rod and cone-mediated vision. FT-001 is administered through a one-time subretinal injection, which places the viral vector directly into the retinal pigment epithelial cells.

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The following diagram illustrates the mechanism of action of FT-001:



Note: ITR = inverted terminal repeats; pA = polyadenylation signal.

Source: Literature Review

Market Opportunities and Competition

RPE65-related IRD represents a significant segment within the global IRD patient population. According to *Worldwide Carrier Frequency and Genetic Prevalence of Autosomal Recessive Inherited Retinal Diseases (2020)*, IRD collectively affects 5 to 10 million patients worldwide, with RP being the most common form and LCA representing the most severe early-onset condition. RPE65-related IRDs cause progressive vision loss that begins with night blindness in childhood and typically advances to complete blindness by early adulthood. The number of patients with RPE65-related IRD was approximately 51.5 thousand globally and 7.9 thousand in China in 2025.

The current treatment landscape for RPE65-related IRDs remains severely limited. Conventional management relies on supportive care, including nutritional supplements and lifestyle modifications, which may slow but cannot halt disease progression. In 2017, the FDA approved Luxturna® as a treatment option in the United States, validating the efficacy of RPE65 gene therapy. However, Luxturna® is currently priced at approximately US\$850,000 per treatment and is not approved in China. A vast unmet medical need persists for Chinese and global patients.

FT-001 is positioned as a potential candidate to address this gap. Building upon the proven mechanism of action established by Luxturna®, FT-001 incorporates several key innovations including a manufacturing process that significantly reduces production costs. This breakthrough would significantly enhance treatment accessibility and commercial viability.

The following charts illustrates the global competitive landscape of FT-001 as of the Latest Practicable Date, according to Frost & Sullivan:

Approved Drug

Brand Name	Drug Name	Company	Vector Type	Manufacturing System	Target	First Approved Date	Country	Route of Administration	Strength	Price	Annual sales in 2025 (million USD)
LUXTURNA®	Voretigene neparvovec	Roche	AAV2	HEK293	RPE65	2017-12-19 2018-11-22 2023-06-01	US Europe Japan	Subretinal	0.5 ml	850,000 USD	46.6

Source: CDE, Frost & Sullivan Report

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Drugs under Development

Route of Administration	Drug Name	Company	Target	Vector type	Phase	First Posted Date	Country	Manufacturing System
Subretinal	LX101	Innostellar Biotherapeutics	RPE65	AAV2	Phase III	2024-10-10	China	NA
	FT-001	Frontera Therapeutics	RPE65	AAV	Phase III IND Approval	2025-09-26	China	Bac/Sf9
					Phase I IND Approval	2022-07-19	US	
	HG-004	HuidaGene Therapeutics Co., Ltd.	RPE65	AAV9	Phase I/II	2023-06-18	China, US	NA

Source: Clinicaltrial.gov, CDE, Frost & Sullivan Report

Key Advantages

FT-001 has exhibited potential with the following key advantages:

- **Optimized Vector Design for High and Durable Efficacy.** FT-001 utilizes an rAAV vector engineered with a highly efficient expression cassette. This includes a codon-optimized and CpG-reduced human RPE65 gene and an optimized promoter and intron working in concert to drive robust, high-level and sustained transgene expression.
- **Comparable or Efficacy to Existing Therapy.** In Phase I/II clinical trials, FT-001 exhibited clinical benefits that are comparable to those achieved with Luxturna[®] based on a non-head-to-head comparison. In particular, FT-001 demonstrated similar or better improvements in key efficacy endpoints, such as the Mobility Test (“MT”) and full-field stimulus threshold (“FST”), which are established measures of functional vision and retinal sensitivity, respectively.
- **Significantly Improved Accessibility.** Due to our cost-efficient manufacturing system, by our estimate, FT-001 achieves a reduction in direct production cost by as much as 90% compared to the only gene therapy treatment option approved in the United States and Europe for the target disease of FT-001. This overcomes a major barrier to patient access, enabling a commercially viable and sustainable treatment that can be accessed by a broad patient population in China and globally.

Summary of Clinical Trial Data

Phase I Clinical Trial

Trial design. The Phase I clinical trial of FT-001 was an open-label, dose-escalation study conducted in participants aged 8 to 45 years with biallelic RPE65 mediated IRD. Three dose cohorts were established: (i) low-dose group: 1.5×10^{10} vg/eye, (ii) medium-dose group: 7.5×10^{10} vg/eye, and (iii) high-dose group: 1.5×10^{11} vg/eye, with participants receiving a single subretinal injection of FT-001 in one eye. A total of nine participants has been enrolled and randomly assigned in a 1:1:1 ratio into these three groups, with each group comprising three participants.

Key inclusion criteria for the trial include but are not limited to (i) male and female participants aged 8 to 45 years old, (ii) clinically diagnosed with LCA2 or RP caused by confirmed biallelic RPE65 mutations, and (iii) both eyes’ vision were below 20/60. Key exclusions criteria for the trial include but are not limited to (i) participants have other interfering ocular diseases that may affect the study results, (ii) participants have other retinal degenerative diseases, (iii) participants had relevant treatment record and/or allergies, including recent eye surgeries, other clinical trials, or allergies to materials used in the trial, and (iv) anti-AAV2 neutralizing antibody titer greater than 1:1,000.

After receiving FT-001, the last participant completed 8 weeks of observation, and, according to the CDE-approved trial protocol, an iDMC meeting was hold to review the

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safety and tolerability data of all participants and confirm the initiation of the Phase II dose-expansion study. Meanwhile, all participants were required to complete 52 weeks of follow-up. Participants who completed the Week 52 visit or withdrew early entered the long-term follow-up period until 5 years after FT-001 injection.

Trial objectives. The primary objectives were to evaluate the safety, tolerability, and preliminary efficacy of FT-001. Primary endpoints relate to safety and tolerability within 28 days of injection, including DLT and incidents of AEs and SAEs. Secondary endpoints relate to preliminary efficacy (e.g. MT changes from baseline), immunogenicity and AAV shedding within 12 weeks.

Trial status. The clinical trial was initiated in January 2023 and completed in October 2023. The iDMC meeting then evaluated the primary endpoints, which are the only prerequisites for the initiation of Phase II clinical trials, confirmed this initiation. Furthermore, secondary endpoints were assessed in December 2023 and met our trial objectives. All participants are undergoing five years of long-term follow-up.

Safety data. The results of the Phase I clinical trial demonstrate a favorable safety and tolerability profile of FT-001. No DLTs were observed. Majority of TEAEs were related to the surgical procedure of subretinal injection such as conjunctival congestion, conjunctival hemorrhage, lens opacity and anterior chamber cells, and have been resolved without intervention or using topical steroid. No RPE atrophy or pigmentation was reported in all participants through the long-term follow-up. Three participants (one in the low-dose group and two in the high-dose group) reported AEs in the severity of Grade 3 or above, including retinal detachment, visual deterioration and ear swelling. Among them, only retinal detachment observed in the low-dose group was assessed to be related to FT-001. There was no adverse event that led to patient withdrawal or study discontinuation.

With respect to AAV shedding within 12 weeks, no AAV shedding was detected in the peripheral blood of participants following FT-001 administration. Transient, low concentrations of vector genomic DNA were detected in the tears of the study eye and/or fellow eye of the majority of participants, but no sustained AAV shedding was observed.

Phase II Clinical Trial

Trial design. The Phase II clinical trial of FT-001 was an open-label, dose-expansion study conducted in participants aged 8 to 45 years with biallelic RPE65 mediated IRD. In the Phase II trial, five eligible participants from the Phase I trial received a subsequent injection of the high dose (i.e. 1.5×10^{11} vg/eye) in their contralateral eye.

Key inclusion criteria for the trial include but are not limited to (i) having participated in the Phase I clinical trial, and (ii) confirmed to have sufficient functional retinal cells. Key exclusion criteria for the trial are the same as the exclusion criteria for the Phase I clinical trial.

After receiving FT-001, all participants completed 52 weeks of follow-up to assess the safety, efficacy, immunogenicity and AAV shedding of FT-001. Participants have entered the long-term follow-ups up to 5 years after completing the Week-52 visit or withdrawing early.

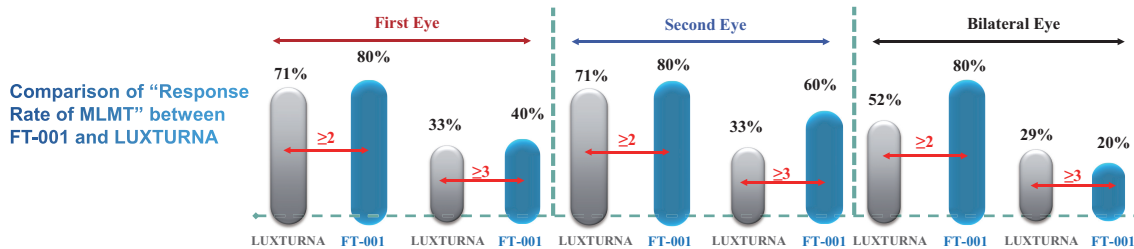
Trial objectives. The primary objectives were to evaluate the safety, tolerability, and efficacy of FT-001. Primary endpoints relate to efficacy (changes in MT from baseline) at Week 52 and safety within 52 weeks of injection. Secondary endpoints relate to efficacy, immunogenicity and AAV shedding within 52 weeks.

Trial status. The Phase II clinical trial was initiated in December 2023 and completed in February 2025. Following trial completion, all endpoints met our trial objectives. All participants are undergoing five years of long-term follow-up.

Efficacy data. The results of the Phase II clinical trial indicate robust and clinically meaningful efficacy.

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The following diagram provides a non-head-to-head comparison between the combined Phase I/II clinical trial results of FT-001 and Luxturna in “response rate”, a measure of the percentage of participants who see at least two light levels of improvements from baseline in the multi-luminance mobility test (“MT”) at Week 52.



Note: Clinical data are not from head-to-head clinical trials, thus not directly comparable.

Source: Company Data, Literature Review

Safety data. The results of the Phase II clinical trial demonstrate a favorable safety and tolerability profile of FT-001. No DLTs were observed. No Grade 3 or above AEs were observed throughout the study. There was no adverse event that led to patient withdrawal or study discontinuation.

With respect to AAV shedding within 52 weeks, no AAV shedding was detected in the peripheral blood of participants following FT-001 administration. Transient, low concentrations of vector genomic DNA were detected in the tears of the injected eye and/or non-injected eye of the majority of participants, but no sustained AAV shedding was observed.

Material Communications and Next Steps

FT-001 received Breakthrough Therapy designation from the CDE of the NMPA in June 2025. We have completed Phase I/II clinical trials in China in February 2025 and our Phase III clinical trial plan has been approved by the CDE in September 2025. We have not confirmed the timeline by which we will continue the clinical development of FT-001 in China and expect to flexibly adjust our timeline based on the amount of resources at our disposal, the clinical progress of other drug candidates, and other external factors. We have not confirmed specific plans to further develop FT-001 in the near term primarily because we allocated resources to prioritize the clinical development of our Core Products which we expect to provide better returns on our investment: the prevalence and total addressable markets of the targeted indications of our Core Products are more significant than those of RPE65-related IRD, and there is already an approved gene therapy product treating RPE65-related IRD. For the avoidance of doubt, our decision is not attributable to any safety or efficacy results of FT-001, and the development of FT-001 has not had any material adverse impact on our operation and business prospect or the clinical development of our other gene therapy candidates.

We expect to consider business development opportunities to facilitate the roll-out of FT-001 going forward. We may also consider how to utilize favorable policies, such as within selected industry Pilot Zones in China where certain treatments are allowed before NMPA approval.

FT-001 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other Candidate for Ophthalmic Diseases

FT-023

FT-023 is a gene therapy candidate in the preclinical stage for treating nAMD, DME and DR. FT-023 is administered through intravitreal injections and focuses on multiple

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biological pathways including VEGF inhibition as well as two additional complementary therapeutic mechanisms. Compared with anti-VEGF therapies, FT-023 is expected to have broader and more sustained efficacy on nAMD and DME patients.

Published literature suggests that approximately 20% to 40% of nAMD patients and 30% to 50% of DME patients globally may demonstrate inadequate or suboptimal response to anti-VEGF therapies, and similar unmet needs have also been observed in clinical practice in China. With a mechanism of action that differs from that of FT-003 and targets two additional biological pathways, FT-023 has the potential to become an effective cure to these nAMD and DME patients. We expect to enroll participants with different characteristics for the clinical trials of FT-023 and FT-003, and evaluate their efficacy and safety independently. While FT-003 is intended to target patients who response adequately to anti-VEGF therapy and to provide a durable, low-burden therapy alternative to repeated anti-VEGF injections, FT-023 is intended to target patients with inadequate or suboptimal responses to anti-VEGF therapy. As we deliberately differentiated the target patient segment of FT-023 and FT-003, we do not expect the two product candidates to have material cannibalization with each other.

To date, pre-clinical pharmacological evaluation results from acute or chronic retinal neovascularization rabbit models demonstrated that FT-023 drug candidates, when compared to the positive control aflibercept, exhibited sustained inhibition of vascular leakage. These findings suggest that FT-023 not only blocks VEGF pathway but may also restore the retinal vasculature integrity and decrease the retinal vascular inflammation, thereby achieving inhibition of neovascularization and suppression of edema.

Other Candidates for Cardiovascular Diseases

For cardiovascular diseases, our pipeline includes gene therapies for HCM caused by mutations in the MYBPC3 gene and ARVC caused by mutations in the PKP2 gene, both of which are severe, genetically driven conditions with limited treatment options and significant unmet need.

FT-017

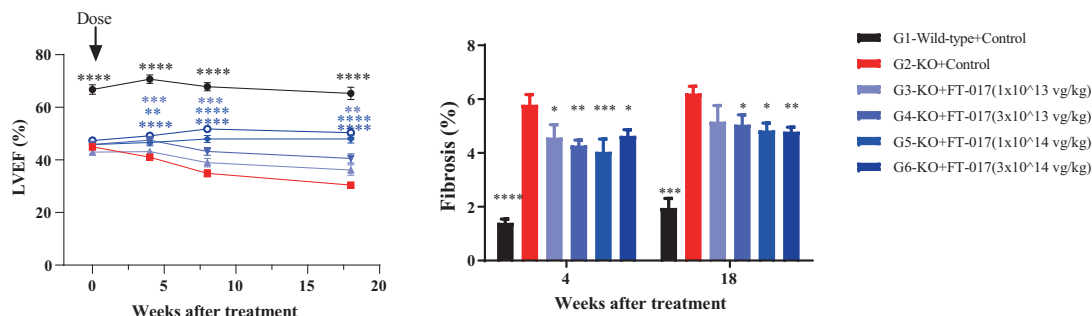
FT-017 is an rAAV gene therapy candidate developed for the treatment of HCM caused by mutations in the MYBPC3 gene. HCM is a prevalent hereditary cardiovascular disorder characterized by abnormal thickening of the ventricular walls, most notably the left ventricle, and is associated with a heightened risk of atrial fibrillation, stroke, heart failure, and sudden cardiac death. The global burden of HCM is significant, with 17.9 million patients worldwide, including 3 million in China in 2025. Among HCM patients, HCM caused by mutations in the MYBPC3 gene is recognized as one of the most common genetic causes of HCM, with 7.7 million patients worldwide, including approximately 1.2 million in China in 2025. Despite the availability of symptomatic treatments and surgical interventions, there are currently no approved therapies that directly address the underlying genetic cause of MYBPC3-mutant HCM, representing a substantial unmet medical need.

FT-017 is designed with a cardiac-specific promoter to ensure targeted expression of a codon-optimized human MYBPC3 gene encoding cardiac myosin binding protein C (“cMyBP-C”), exclusively in cardiomyocytes, thereby minimizing off-target effects in non-cardiac tissues such as the liver and skeletal muscle. The therapy is administered via intravenous injection, enabling systemic delivery and efficient transduction of heart tissue. This targeted approach is intended to restore the expression of cMyBP-C, a critical component for normal cardiac muscle contraction and structure.

Preclinical studies have demonstrated that FT-017 can enable expression of cMyBP-C protein in the heart, leading to improvements in cardiac function and structure. In MYBPC3-knockout mouse models, FT-017 administration resulted in marked increases in left ventricular ejection fraction (“LVEF”), reduction of cardiac fibrosis, and normalization of heart morphology. These therapeutic effects were observed in neonatal, juvenile, and adult mice, underscoring the potential of FT-017 to benefit a broad spectrum of HCM patients. Importantly, tissue-specific expression was confirmed, with minimal to no detectable

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transgene expression in non-cardiac tissues, supporting a favorable safety profile. Toxicology studies in non-human primates (“NHPs”) further corroborated the safety of FT-017, with no hepatotoxicity, thrombotic microangiopathy (“TMA”), cardiotoxicity, or neurotoxicity observed.



Data are presented as mean $\pm$ SEM. Week 4/8/18: N=8~24

(* P <0.05, ** P <0.01, *** P <0.001, **** P <0.0001 vs. G2 Model+Vehicle, Two-way ANOVA and Dunnett’s test)

Source: Company Data

FT-017 has achieved key regulatory milestones, having received IND clearance from both the NMPA and the FDA in April 2025. It is the first rAAV gene therapy for MYBPC3-mutant HCM to enter clinical trials in China, positioning FT-017 at the forefront of innovation in the field of genetic cardiomyopathies.

Based on our current development plan, we expect to commence the Phase I clinical trial of FT-017 in China in the fourth quarter of 2027 and to begin Phase II clinical trial of FT-017 in China in the fourth quarter of 2028. We currently expect to commence the Phase I clinical trial in the United States in the fourth quarter of 2027.

FT-018

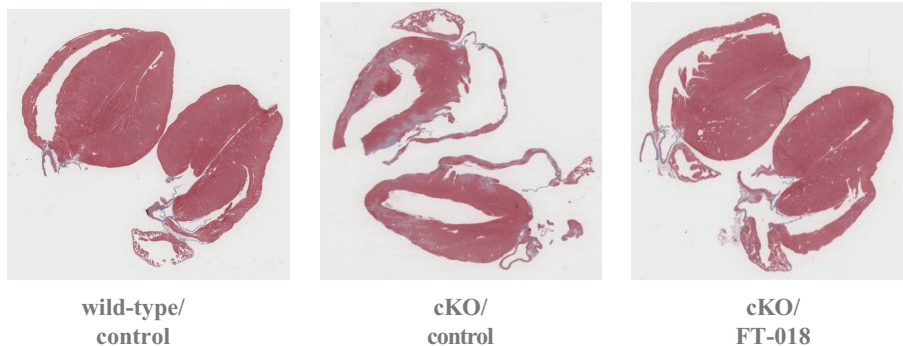
FT-018 is a preclinical-stage, rAAV gene therapy candidate for treating ARVC caused by mutations in the PKP2 gene. ARVC is an inherited myocardial disease that significantly increases the risk of arrhythmic sudden cardiac death, particularly in young individuals and athletes. The disease is characterized by progressive loss of cardiac muscle, fibrofatty replacement, ventricular arrhythmias, and heart failure. The global burden of ARVC is significant, with 1.8 million patients worldwide in 2025, including approximately 0.4 million in China. Mutations in the PKP2 gene are the most common genetic cause of ARVC, yet there are currently no approved therapies that address the underlying molecular defect, highlighting a critical unmet need. It is estimated that there are 541.9 thousand patients with ARVC caused by mutations in the PKP2 gene worldwide in 2025, including over 164.4 thousand in China.

FT-018 employs an optimized and sophisticated vector design to deliver a functional PKP2 gene specifically to cardiac muscle tissue. The gene cassette is engineered to ensure robust and durable expression of PKP2 protein in the heart, thereby restoring normal cell-cell adhesion, contractile function, and electrical stability of the myocardium. By targeting the root cause of ARVC, FT-018 aims to halt or reverse disease progression, prevent further tissue fibrosis, and improve overall cardiac function.

Preclinical studies in PKP2 conditional knockout (“cKO”) mouse models have demonstrated that FT-018 treatment can lead to restoration of cardiac structure and function. Administration of FT-018 resulted in robust cardiac-specific expression of PKP2, reduction of myocardial fibrosis, normalization of heart failure biomarkers, and a marked increase in survival rates among treated animals. Histological analyses confirmed improved heart morphology and reduced pathological remodeling. In addition, toxicology studies in wild-type mice have shown that FT-018 is well-tolerated, with no significant safety concerns

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observed following systemic administration. The following diagrams illustrate the heart structure of a wild-type control model, the heart structure of a control model 4 weeks after PKP2 knockout, and the heart structure of a model that received FT-018 4 weeks after PKP2 knockout, showing significant improvement in heart structure and reduction in fibrosis.



Source: Company Data

FT-018’s vector design and compelling preclinical efficacy and safety data support its potential as a gene therapy for PKP2-associated ARVC. The program is advancing through preclinical development, with the goal of initiating clinical studies to address the substantial unmet needs of patients with this life-threatening cardiovascular disorder.

Other Early-stage Drug Candidates

In addition to our drug candidates discussed above, we are leveraging the proven versatility of our EXACTE™ R&D and AAVANCE™ manufacturing platforms to explore the development of other drug candidates targeting ophthalmic, cardiovascular, neurological and hematological diseases, which are currently in preclinical or early clinical stages. This approach underscores the broad applicability and extendibility of our platforms, enabling us to address other categories of diseases beyond our initial focus areas. Below we set forth two examples of these early-stage drug candidates.

FT-019

FT-019 is an early-stage drug candidate designed to address an undisclosed slow degenerative ophthalmic indication characterized by substantial unmet medical need and the absence of curative treatment options. It is administered through subretinal injections. Our strategy combines modulation of multiple disease pathways to achieve greater therapeutic efficacy.

FT-022

FT-022 is an early-stage drug candidate designed to address Parkinson’s disease, a progressive neurological condition characterized by the gradual loss of specific neurons critical for motor function. Current therapies provide only symptomatic relief and do not address the underlying disease mechanisms. Our gene therapy approach is designed to simultaneously modulate multiple key disease pathways to restore neuronal function and slow degeneration. The route of administration for FT-022 is yet to be confirmed. If successful, it has the potential to deliver durable therapeutic benefits.

OUR TECHNOLOGY PLATFORMS

The EXACTE™ R&D Platform

Overview

EXACTE™ is our in-house developed rAAV gene therapy R&D platform. EXACTE™ integrates advanced technologies and methodologies from vector design and engineering to

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candidate selection and preclinical validation. As of the Latest Practicable Date, all six of our in-house developed rAAV gene therapy candidates in our product pipeline have been identified and selected through our EXACTE™ R&D platform.

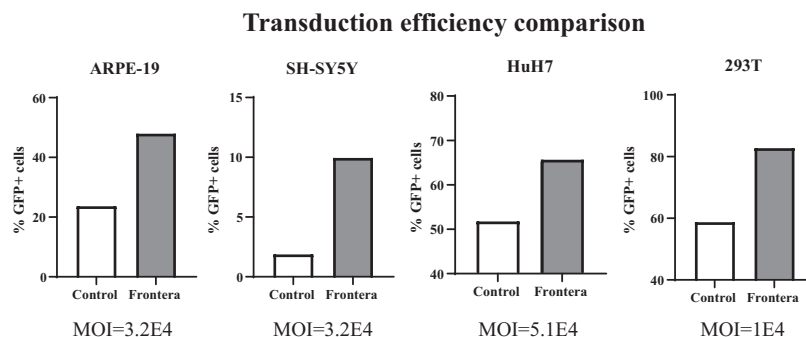
Key Features

Capsid Engineering

EXACTE™ employs a rational design and mutagenesis approach to engineer AAV capsid variants with improved tissue tropism and transduction efficiency. Tissue tropism refers to the ability of the rAAV vector to selectively target and transduce specific tissues or cell types, which is critical for maximizing therapeutic efficacy and minimizing off-target effects or unwanted distribution or transduction in non-target tissues. Transduction efficiency describes how effectively the rAAV vector delivers its genetic payload into the target cells, directly impacting the potency of the gene therapy.

EXACTE™ also incorporates baculovirus rep/cap vector design which is specifically designed for compatibility with our Bac/Sf9-based AAVANCE™ manufacturing platform. This enables the production of rAAV vectors with higher biological activity and improved particle integrity.

The design of baculovirus rep/cap vectors we have achieved through EXACTE™ has led to significant improvements in the production and functional quality of rAAV vectors using the Bac/Sf9-based rAAV gene therapy production infrastructure. Specifically, our rep/cap vector design has resulted in a more favorable ratio of AAV capsid proteins VP1, VP2, and VP3, which are critical for the structural integrity and infectivity of the viral vector. *In vitro* studies demonstrate that these AAV2 vectors exhibit higher infection efficiency across a variety of cell types. This means that, for a given dose, a greater proportion of target cells are successfully transduced, leading to more robust gene expression. The enhanced transduction efficiency illustrates the performance of the optimized AAV2 vectors compared to those produced with the control design.



Source: Company Data

Payload Engineering

EXACTE™ utilizes sophisticated strategies to optimize the genetic payload for each therapeutic candidate:

- **Codon optimization** is performed to maximize the expression of the therapeutic gene in the target tissue, ensuring that the delivered gene is efficiently translated into the desired protein.
- **CpG motif reduction** is carefully managed to lower the risk of immune responses against the AAV genome. CpG motifs are short DNA sequences that can trigger innate immune activation; reducing their frequency helps minimize immunogenicity and potential adverse reactions.

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- **Regulatory elements** — including promoters, introns, and polyadenylation signals — are systematically selected and engineered to achieve either broad or tissue-specific expression profiles, as required by the therapeutic indication. This allows for precise control over where and how much of the therapeutic protein is produced in the body.
- **Protein engineering** is also applied to enhance the function or activity of the expressed therapeutic protein, further improving the clinical potential and durability of gene therapy.

These strategies collectively contribute to higher and more sustained therapeutic protein levels, improved safety, and reduced risk of immune-related side effects.

Candidate Screening

EXACTE™ integrates comprehensive *in vitro* and *in vivo* screening systems to evaluate the distribution, efficacy, safety, and toxicity of candidate constructs at the preclinical stage. This robust screening framework enables the identification of lead drug candidates with optimal therapeutic profiles and de-risked safety characteristics, thereby enhancing the likelihood of successful translation into clinical development. The platform’s screening capabilities support rapid iteration and data-driven decision-making, allowing for efficient progression from discovery to IND-enabling studies. By employing high-throughput and systematic screening, EXACTE™ accelerates the selection of the most promising candidates, reduces development timelines, and increases the probability of clinical and commercial success.

The AAVANCE™ Manufacturing Platform

Overview

We built the in-house developed AAVANCE™ manufacturing platform to enable scalable, high-quality and low-cost production of rAAV gene therapy products. As the only company in China with in-house, clinical-stage, Bac/Sf9-based large-scale GMP manufacturing capabilities, we have established a robust infrastructure that supports the entire development continuum — from preclinical research through commercial-scale production. As of the Latest Practicable Date, all six of our in-house developed rAAV gene therapy candidates in our product pipeline have relied on our AAVANCE™ manufacturing platform for the production of gene therapy drug products and related materials for clinical trial use.

Bac/Sf9-based production requires considerable know-how and upfront investment to implement, which we believe constitutes a significant barrier to entry for potential competitors, particularly for those who have already implemented a different production system.

Key personnel who contributed to the development of the AAVANCE™ manufacturing platform include Peng Yang, our head of manufacturing, Aiqun Li, our head of quality control, and certain former employees including Hongxiang Lu, Ting Yang and Yiling Fang. Peng Yang and Aiqun Li have been responsible for our manufacturing activities, including continuous optimization of the manufacturing platform, since they joined us in 2021. In addition, we previously had a U.S.-based process development and analytical development team which worked on the early development of the AAVANCE™ manufacturing platform. Key members of this team include Hongxiang Lu, our former senior vice president who was responsible for overall management of the daily operations of our process development and analytical development team, Ting Yang, our former senior director who was responsible for upstream and downstream process development, and Yiling Fang, our former senior director who was responsible for analytical method development and sample testing during process development. The above three individuals left our Company between late 2024 and early 2025, and their departure did not have a material adverse effect on our R&D or manufacturing capabilities, as (i) we have already developed sophisticated and commercial-ready manufacturing methods of our products under the leadership of our head

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of manufacturing, Peng Yang, and head of quality control, Aiqun Li, (ii) the former employees’ responsibilities were naturally absorbed by other team members including Peng Yang and Aiqun Li, and (iii) the former employees were subject to IP assignment provisions assigning all of their rights over the relevant patents to us.

Key Features

Versatility and Safety

We have developed a rhabdovirus-free Bac/Sf9 cell line, verified through rigorous screening and molecular testing, to ensure the safety and reliability of our production system. This feature reduces the risk of rhabdovirus contamination, a known challenge in insect cell-based manufacturing, and underpins the safety profile of our gene therapy products. The AAVANCE™ platform is validated for the production of multiple AAV serotypes (including AAV2, AAV5, AAV8 and AAV9) and their variants, supporting a broad and diverse pipeline of gene therapy candidates. AAVANCE™ has already demonstrated its ability to support the development of multiple gene therapy candidates across diverse therapeutic areas, as reflected in our expanding pipeline. AAVANCE™ has facilitated the rapid progression of candidates from preclinical to late clinical stages. These achievements provide evidence of the platform’s versatility and its capacity to meet both clinical and commercial demands.

Critically, we have attained empty capsid rates below 1%, compared to an industry norm of close to 30% according to Frost & Sullivan. High empty capsid rates are undesirable because they can reduce the overall potency of the gene therapy product by diluting the proportion of active therapeutic vectors and increase the risk of immune responses. By minimizing empty capsid rates, AAVANCE™ ensures that a greater proportion of the manufactured rAAV particles are fully functional, which enhances both the safety and efficacy of the final gene therapy product and supports more cost-effective large-scale production.

Large-Scale Production and Significant Cost Advantages

Our AAVANCE™ manufacturing platform enables high-quality gene therapy production at scale, with exceptional efficiency and cost advantages. AAVANCE™ boasts an industry-leading GMP-compliant production capacity of 200L for intraocular products and 500L for systemically administered products. After accumulating extensive technological expertise, we have demonstrated one-step scale-up from 2L to 500L without loss in yield or quality.

Currently, laboratory-scale rAAV production typically achieves yields in the range of 10^{12} – 10^{14} vg/L; in comparison, our bioreactors achieve upstream production yields of more than 10^{15} vg/L, which places us among the industry leaders in this respect, according to Frost & Sullivan. Our high-yield, high-purity production also facilitates process stability and enables us to reach downstream purification yields of 50%. We manufacture rAAV vectors in either 200L bioreactors for the treatment of ophthalmic diseases or 500L bioreactors for the treatment of cardiovascular diseases. For each batch, the upstream process typically produces 2.0×10^{14} vg/L to 1.0×10^{15} vg/L of culture. After downstream purification, with an overall 30%–50% recovery, each batch yields approximately 1.6×10^{16} to 2.5×10^{17} vg in total. After formulation and fill-finish, one batch typically provides approximately 1,200 to 60,000 filled vials (the exact number depends on the program-specific fill volume and output). We have sufficient capacity to support clinical development and initial commercialization, and Bac/Sf9-based production is more accessible and requires lower media and infrastructure costs to grow as compared to other commonly used methods, which facilitates further expansion when and as needed.

Our cost advantage in developing gene therapy drugs supports lower pricing and higher accessibility. FT-001 achieves a reduction in direct production cost by as much as 90%, by our estimate, compared to the only rAAV gene therapy product approved in the United States and Europe for the target disease of FT-001.

Commercial Readiness and Regulatory Success

Our manufacturing facility in Suzhou is fully GMP-compliant and was designed to meet the regulatory requirements of the FDA, EMA, and NMPA. The facility is equipped to

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support all stages from pilot-scale to GMP commercial production, ensuring consistent product quality and regulatory readiness. We have implemented an integrated QA/QC system that covers the entire manufacturing process, enabling us to maintain a high level of product consistency and quality.

We have already implemented product processes for six programs that satisfy U.S. and Chinese requirements for clinical-trial product quality. Our manufacturing track record demonstrates the robustness and reliability of AAVANCE™, with 10 GMP-compliant batches successfully produced and released at 200L and 500L scale, achieving a 100% success rate.

RESEARCH AND DEVELOPMENT

Overview

We are a biotech company focused on utilizing our EXACTE™ R&D platform and our AAVANCE™ manufacturing platform to develop rAAV gene therapies. We have developed all of our product candidates in-house and we hold the global intellectual property rights to all of them. We solely own all patent applications in connection with our two Core Products filed by us, and have not out-licensed such pending patents to a third party. We are of the view that there are no valid third party patents enforceable against us in connection with any of our two Core Products. Thus, we have full and independent rights to conduct R&D and commercialization of our two Core Products.

To date, we have obtained 12 IND approvals from the NMPA and FDA, making us one of the Chinese rAAV gene therapy development companies with the highest number of IND approvals, according to Frost & Sullivan. Since our inception, we have successfully advanced three drug candidates through clinical development, with one candidate having obtained approval to enter Phase III clinical trials and two candidates having completed Phase II clinical trials, further underscoring our strong track record in drug development. These achievements demonstrate our highly efficient execution capabilities and our ability to collaborate effectively across regions.

In-licensed Methodology

The research and development of rAAV gene therapies generally consist of the development of (i) capsids and (ii) genes of interest within the capsids. We independently developed both the capsids and the genes of interest for all of our product candidates. For FT-001 and FT-002, we licensed a commoditized methodology from a third party, Virovek Inc., relating to the efficient and large-scale manufacturing of AAV capsids, which is independent of the drug candidates’ design, structure or sequence. The resulting capsids produced by the licensor’s patented methodology are not subject to any further patents held by the licensor or other parties, while we own pending patents to FT-001 and FT-002 which consist of the capsids and the genes of interests solely designed and developed by the Company as a whole.

Virovek Inc. is an independent, U.S.-based biotech company which provides similar licenses to multiple other companies globally. The scope of the license is not specific to any indications and is effective worldwide. As the in-license arrangement relates to a methodology instead of a product, there is no development stage applicable to the in-licensed methodology and we have not and do not expect to invest in the R&D of the in-licensed methodology. Our know-how and intellectual properties relating to FT-001 and FT-002 are owned by us and not based on the licensed methodology or subject to any license agreement. Our pending patents for FT-001 and FT-002 do not reference the licensed methodology. We licensed this third-party methodology, which is a commoditized methodology readily available from multiple vendors including a large number of CDMOs in the rAAV industry, because we were at the very early stages of development and believed it was more efficient for us to focus on other, more substantive components of rAAV gene therapy development. Our subsequent development of our own capsids production methodology, which was used in our other Core Product, FT-003, and other product candidates, also confirmed our ability to not rely on the licensed methodology.

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In terms of key rights and obligations of us and the licensor, our payment obligations include (i) a one-off, upfront payment which has been settled, (ii) annual license fees that vary based on the clinical development status of the relevant product, (iii) royalties that equal 1% of net sales of the relevant product for 10 years after the product's commercial sale, or, if later, until the expiration of the licensor's relevant patent right, subject to a reduction of 0.5% of net sales in countries where there is no relevant patent right, and (iv) certain milestone payments linked to the initiation of Phase I and Phase III clinical trials as well as the filing of NDAs in the range of US\$25,000 to US\$100,000. Accordingly, during the Track Record Period, we paid a total of US\$25,000 to the licensor in connection with this license. We will owe additional fees to the licensor after the commercialization of FT-001 and FT-002, including milestone payments and royalty fees as stated above. We may terminate this agreement at any time with 90 days' advance written notice, whereas the licensor can only terminate the agreement for cause. The license agreement is governed under the laws of the Commonwealth of Massachusetts and disputes may be brought in state and federal courts located in Massachusetts.

We do not believe that this license has or will have any material effect on our business operations or our ability to commercialize our drug candidates for the following reasons: (i) we are the sole inventor of the operative components of FT-001 and FT-002 (the design and optimization of the capsids and genes of interests) as discussed above; (ii) the in-licensed methodology is a commoditized methodology provided to us on a non-exclusive basis, and is widely available in the market through a number of gene therapy CDMOs; (iii) for FT-003 and subsequent products in our pipeline, we do not use this in-licensed methodology and instead use our own methodology which is a substitute for the in-licensed methodology; (iv) the amount of fees we paid the licensor is a minute portion of our overall research cost during the Track Record Period; and (v) we are the sole sponsor and sole marketing authorization holder of our Core Products and Key Product, and there is no Joint Steering Committee arrangement in the in-license arrangement which would allow any third party to influence the use of the methodology — we are therefore solely in charge of the clinical development and marketing of FT-001 and FT-002.

R&D Expenses

Our research and development expenses during the Track Record Period mainly included drug discovery, preclinical and clinical trial expenses, manufacturing expenses, registration and regulatory affairs expenses, and staff costs.

For the years ended December 31, 2024 and 2025, our research and development expenses was US\$20.6 million and US\$13.9 million, respectively, representing 74.6% and 73.1% of our total operating expenses, defined as the sum of research and development expenses and general and administrative expenses in the corresponding years, respectively. For the six months ended June 30, 2025 and 2026, our research and development expenses was US\$7.1 million and US\$5.3 million, respectively, representing 72.4% and 68.6% of our total operating expenses, respectively.

For the years ended December 31, 2024 and 2025, we recorded research and development expenses attributable to one of our Core Products FT-002 of US\$2.2 million and US\$1.7 million, respectively, representing 10.6% and 12.5% of our total research and development expenses, respectively. For the six months ended June 30, 2025 and 2026, we recorded research and development expenses attributable to one of our Core Products FT-002 of US\$0.6 million and US\$1.0 million, respectively, representing 8.7% and 18.7% of our total research and development expenses, respectively.

For the years ended December 31, 2024 and 2025, we recorded research and development expenses attributable to one of our Core Products FT-003 of US\$4.0 million and US\$6.0 million, respectively, representing 19.6% and 43.1% of our total research and development expenses, respectively. For the six months ended June 30, 2025 and 2026, we recorded research and development expenses attributable to one of our Core Products FT-003 of US\$2.8 million and US\$3.2 million, respectively, representing 39.5% and 60.8% of our total research and development expenses, respectively.

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For details of our research and development expenses, including research and development expenses attributable to the Core Products, please see “Financial Information — Description of Major Components of Our Results of Operations — Research and Development Expenses.”

R&D Team

As of June 30, 2026, our in-house R&D team consisted of 37 members across China and the United States, over 56% of whom held a doctoral or master’s degree, mainly in medical science, biology, pharmacology, and chemistry and other related fields. The average industry experience of our R&D team is over ten years.

Members of our R&D team have deep scientific talent and extensive experience at multinational pharmaceutical companies. Our R&D team consists of our drug discovery team, preclinical and translational medicine team, clinical development team, and CMC team. In addition, we collaborate with external research partners, such as CROs.

Notably, our research leadership have extensive prior experience in gene therapy research and a demonstrated track record contributing to the advancement of gene therapy drugs. Our in-house R&D team is led by Dr. Xinyan Li, our chief executive officer and chief medical officer, and Dr. Zhongdong Shi, our senior vice president and head of R&D.

Dr. Xinyan Li is responsible for shaping our overall development strategy and providing guidance across key business segments from preclinical study and translational medicine to clinical development, manufacturing, and regulatory affairs. Prior to joining us, Dr. Li had over 20 years of experience in the innovative biopharmaceutical field, with nearly 10 years of experience in scientific research and deep expertise in molecular biology, immunology, and cell and gene therapy. Dr. Li previously conducted research on gene and cell therapy as a visiting scholar at the Faculty of Medicine of the University of Montpellier in France, and has earned multiple prestigious awards for her impactful scientific research in Jiangsu province and Shanghai that honor her contributions to medical research and innovation, including, among many others, the “Pearl Plan” Leading Talents award of the Pudong New Area (浦東新區“明珠計劃”領軍人才) in 2024 and the Double Innovation Talents award of Jiangsu Province (江蘇省“雙創人才”) in 2023. Dr. Li brings extensive experience overseeing global drug development through its full life cycle. While at CARsgen Life Sciences Co., Ltd., Dr. Li led preclinical and clinical operations, medical affairs, and regulatory strategy, and achieved significant milestones, including the IND clearance for CT041 (an anti-CLDN18.2 CAR-T therapy) from the FDA and the NMPA, as well as the initiation of the pivotal Phase II trial of CT053 (a fully human BCMA CAR-T therapy) in China. Dr. Li formulated the development plan for our Core Products back in November 2020, and has consistently led the formulation and execution of our R&D strategy since then. For more details on Dr. Li’s background and how they relate to her work in rAAV based gene therapies with us, see “Directors and Senior Management — Board of Directors — Executive Directors.”

Dr. Zhongdong Shi, one of our earliest employees, leads our research and development strategy and activities and oversees all research and development plans. Dr. Shi has extensive experience from his previous job in viral vector design and production, gene editing and stem cell differentiation and disease modeling, all of which are critical technologies for developing cell and gene therapies. During Dr. Shi’s time in the biotech industry prior to joining us, although the products he developed were stem cell therapies and CAR-T cell therapies, his work focused on vector designs, including lentiviral vector and AAV vector, and the use of those viral vectors to deliver genes of interest into stem cells and T cells to produce cell therapy products. These direct hands-on experiences in viral vector design, production and application enabled Dr. Shi to become an integral part of our endeavor to build up our R&D capabilities in the early days, as well as a key contributor to the initial discovery and development of our Core Products. Throughout his time with us, Dr. Shi has consistently steered our research and development focus and resources towards greater impact and more efficient clinical development. Dr. Shi is an inventor of our material patents and the sole developer of EXACTE™, our R&D platform.

Our preclinical studies and translational medicine function is led by senior director Dr. Chao Ren, who holds a Ph.D. in Biology from Warwick University and has 13 years of

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experience at leading biotechnology companies. Our clinical operations function is led by senior director Mr. Minghui Xue, who brings 16 years of experience from several industry-leading biotech companies. Our CMC function is led by the head of manufacturing, Mr. Peng Yang, who has 17 years of experience at top biotechnology companies. Our quality function is led by Dr. Aiqun Li, who earned a Ph.D. in Cell Biology from Purdue University and has 16 years of experience at leading biotechnology companies and research institutions. Together with Dr. Li and Dr. Shi, the aforementioned employees are the key R&D personnel of the Company during the Track Record Period and up to the Latest Practicable Date (the “**Key R&D Personnel**”). During the Track Record Period and up to the Latest Practicable Date, all Key R&D Personnel who led the discovery and development of our Core Products, FT-002 and FT-003, remained employed by us. They have been extensively involved in developing our Core Products from their inception and in guiding the development of the Core Products through to IND approval and clinical trial execution.

Between March 2021 and May 2023, Dr. Yong Dai served as our then chief executive officer. Between May 2022 and January 2024, Dr. Dean Falb served as our then chief scientific officer. Around the time Dr. Dai joined us and before Dr. Falb joined, Dr. Li and our R&D team had already substantially completed the viral vector construction and screening for our Core Products, and commenced preclinical studies on efficacy and safety shortly thereafter. During their time with us, both Dr. Dai and Dr. Falb were based in the United States and were primarily responsible for providing leadership and managerial oversight in drug discovery and early-stage pre-clinical research, consistent with our focus in the United States at the time on drug discovery. Specifically, they were involved in initial early-stage decisions such as selecting the initial technology pathways and formulating R&D strategies together with others including our then chief medical officer, Dr. Xinyan Li. As our then chief executive officer, Dr. Dai was responsible for and contributed to managing our overall development, coordinating internal and external resources, facilitating communication between our China and U.S. teams, and overseeing our finances. As our then chief scientific officer, Dr. Falb was responsible for and contributed to facilitating the preclinical efficacy and safety studies of our Core Products which had been initiated before he joined us. Meanwhile, specific drug discovery work, such as early vector construction and design, gene-of-interest design, and the design and establishment of early preclinical studies, was led and completed by Dr. Li and Dr. Shi. The design and establishment of our EXACTE™ rAAV gene therapy R&D platform was carried out and implemented by Dr. Shi. The manufacturing and production aspects of our development have been led by Dr. Li since the inception of our manufacturing capabilities. In 2023 and 2024, Dr. Dai and Dr. Falb left the Company due to our strategy adjustment and re-balancing of focus across China and the United States as a result of our drug discovery progress, subsequent selection of technology pathway and organic development of the Core Products towards clinical trials in China. Following their departure, Dr. Xinyan Li and Dr. Zhongdong Shi, who had been performing relevant managerial, scientific and pre-clinical development functions in conjunction with Dr. Dai and Dr. Falb prior to their departure, naturally absorbed their responsibilities. The Phase I clinical trials for our Core Products were initiated in April 2024 for FT-002, August 2023 for FT-003 for nAMD and December 2023 for FT-003 for DME, all after the departure of Dr. Dai and around the time of Dr. Falb’s departure. Neither Dr. Dai nor Dr. Falb is an inventor of any of our patents. As a result of our strategic adjustment and re-balancing of focus, our US personnel is primarily focused on preclinical research while clinical-stage development is primarily conducted in China. The departure of Dr. Dai and Dr. Falb did not have a material adverse impact on our R&D capabilities or our clinical development progress.

In addition, as listed in “Appendix IV. Statutory and General Information — B. Further Information About Our Business — 2. Intellectual Property Rights — (c) Patents,” both Wei Zhao and Sebastian Aguirre Kozlouski were our former consultants and co-inventors of FT-001 with Dr. Shi. Zhao is also a co-inventor of FT-002 and FT-003 with Dr. Shi. In the early stages of our Company (e.g., 2019 and early 2020), we engaged external consultants to progress early-stage R&D preparations. Both Zhao and Kozlouski were engaged as external consultants in such capacity. While both Zhao and Kozlouski made early contributions, Dr. Shi led the overall development of FT-001, FT-002 and FT-003. Zhao is listed as a co-inventor for the above products as he participated in the early-stage research, project initiation and CRO selection related to the relevant products; Kozlouski is listed as a co-inventor for FT-001

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as he participated in the project initiation of FT-001. Both Zhao and Kozlouski have executed IP assignment agreements assigning their rights over relevant patents to us. Zhao and Kozlouski have not been involved in the development of our drug candidates since April 2021 and March 2020, respectively, and our continued success in the development of our Core Products and Key Product since then confirms our independent R&D capabilities. During Zhao's time at the Company, he also served as a partner for Creacion, one of our Founding Shareholders. Save for the above, neither Zhao nor Kozlouski had any other relationship with the Company, our directors, senior management and/or substantial shareholders.

R&D Centers

We capitalize on the strengths of global hubs of biotechnological research in both the United States and China while maintaining a unified global R&D strategy and leveraging the greater efficiency and cost-effectiveness of clinical trials in China.

Our Boston center is responsible for drug discovery and early-stage research, including capsid screening and viral vector construction and optimization. Our Shanghai center handles preclinical study and clinical trials, including investigator initiated trials, IND applications and the clinical trials themselves. Our Suzhou center fulfills the manufacturing needs of our preclinical and clinical trials while preparing for commercial-scale production. This division of focus allows each team to contribute its strengths to the overall development process while ensuring executional efficiency through the entire workstream.

Up to mid 2024, our Boston center consisted of a few different functions, including vector research and early development, bioanalytical, *in vivo* pharmacology, and CMC related process development and analytical development. In line with the clinical progress of our Core Products in 2024, we strategically shifted our focus from preclinical studies towards later stage drug development. Accordingly, we restructured our team in Boston for a leaner team with greater organizational efficiency. The above mentioned functions were consolidated into a single R&D team with expertise across research, discovery, *in vivo* pharmacology, bioanalytical assay development and early process development. As of December 31, 2024 and 2025 and June 30, 2026, we had 8, 5 and 4 employees in the Boston center, respectively. The restructuring did not have a material adverse effect on our business operations or R&D capabilities, as further discussed below. In addition, in September 2025, we relocated our laboratory in Boston to a new, smaller location in Watertown, Massachusetts, a nearby city, and disposed certain obsolete equipment through a local agent handling laboratory and biotech equipment sales in line with our shift in focus and push towards greater efficiency. We engaged this agent by comparing fee quotes from a few alternatives, and the agent sold the equipment to customers whose identities were not revealed to us. We recorded related losses of US\$3.6 million as "losses on disposal of property and equipment", an item under "other gains and losses." The relocation did not have a material adverse impact on our business operations and financial performance.

Despite the reduction in team size and relocation of laboratory, our Boston center, now consisting of multidisciplinary experts, continues to excel at research and drug discovery. For example, after the restructuring in mid 2024, our Boston center has accomplished key milestones including initiating two new early programs, FT-019 and FT-023, establishing capsid discovery capabilities that have produced AAV2 variants for intravitreal delivery, and filing three new patent applications. As for the development of our existing product candidates in the U.S., particularly the clinical trials and registrations of our Core Products, we intend to collaborate with local CROs who assist in site management, patient recruitment, drug candidate management, pharmacovigilance, data management, and registration, among others. Drug candidates used in such clinical trials will be manufactured by our China-based facility. Our Boston center will continue to focus on early-stage R&D activities, including vector construction and screening, GOI optimization, early process and analytical development, patent applications and facilitation of IND applications, all of which have been completed with respect to our Core Products. During the Track Record Period, we did not have operations or key facilities in the United States outside of the Boston region as discussed above.

R&D Process

We have established a comprehensive in-house R&D system that governs all critical aspects of rAAV gene therapy discovery and development.

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Drug Discovery

Prior to initiating a gene therapy R&D program, our multidisciplinary team of scientists leverages deep expertise in molecular genetics, biology and clinical medicine, as well as the advice from patent lawyers, to identify and prioritize genetic targets with high therapeutic potential. For each selected target, we conduct a thorough assessment of disease prevalence, unmet medical need, scientific rationale, patent landscape, competitive environment, and potential development risks. This comprehensive evaluation positions our programs for clinical and commercial success.

Upon determination of the target indication, we employ our EXACTE™ R&D technology platform to design and engineer gene therapy candidates. This process includes rational capsid engineering to optimize tissue tropism and transduction efficiency, as well as payload engineering to achieve robust and sustained transgene expression.

Translational Medicine and Preclinical Research

Our translational medicine team bridges the gap between preclinical research and clinical application, supporting the design of robust clinical programs and providing scientific interpretation of preclinical and early clinical data. Their interdisciplinary research encompasses a wide range of studies from pharmacokinetics, pharmacodynamics, safety and biomarker development, to quantitative and clinical pharmacology. Our translational medicine team plays a key role in improving the success rates, time-efficiency and cost-effectiveness of our clinical trials.

During the preclinical stage, we conduct comprehensive pharmacology, pharmacokinetics, biodistribution, and toxicology studies, both *in vitro* and *in vivo*, to evaluate the safety and efficacy of our gene therapy candidates. We further assess immunogenicity, biodistribution, and long-term functional outcomes in relevant disease models. Only those candidates demonstrating strong preclinical profiles and a clear path to clinical translation are advanced into IND-enabling studies and subsequent clinical development. This integrated and iterative approach enables us to efficiently discover and develop gene therapies that address significant unmet medical needs.

Clinical Development

During clinical trials, we maintain close collaboration with leading hospitals, research institutions, and principal investigators to ensure adherence to study protocols and good clinical practice (“GCP”) guidelines. Our clinical operations team is responsible for site management, participant recruitment, and data management, enabling high-quality and timely execution of clinical studies. We select trial sites and investigators based on their expertise, resources, and access to relevant patient populations.

The clinical development team manages all stages of clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. Each of our clinical development programs is led by a program leader who (i) formulates a clinical development plan, (ii) designs the trial protocol, (iii) bears responsibility for pharmacovigilance, and (iv) oversees the trial execution, all with support from other team members. We employ an adaptive clinical trial design strategy to achieve efficiency in product development processes and potentially accelerate approvals for our drug candidates.

CMC

Our CMC team constitutes an integrated part of our R&D functions. CMC performs vital roles including scale-up, optimization, characterization and validation, control method development and validation, and technology transfer and assessment. Our CMC team provides preclinical and clinical support throughout the product development process.

Our CMC capabilities include preclinical and clinical support and commercial manufacturing.

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Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates, including developing registration strategies, assembling application dossiers for INDs, addressing inquiries from regulatory authorities, and monitoring ongoing R&D projects to ensure compliance with regulations. Our regulatory team members are deeply familiar with regulatory processes of relevant governmental agencies, such as the NMPA and the FDA.

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 use CROs for the OCT image review, biological sample testing and statistical analysis of clinical data. Previously, we used CRO for clinical management for the Phase I clinical trial of FT-001 in China. We also used the same CRO for clinical management of two IITs for FT-002 and FT-003 respectively in China.

We select our CROs weighing various factors, such as their qualifications, academic and professional experience, industry reputation, and the scope, depth, and quality of their service and product offerings. Given our arrangements with CROs are generally project-based and non-exclusive, and comparable service providers are readily available in the market, our collaboration with CROs does not constitute undue reliance on CROs. We also place a high value on our CROs’ ability to facilitate optimal site selection, timely participant recruitment, and efficient conduct of complex preclinical and clinical trials. We supervise these CROs to ensure that they perform their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the data resulting from our trials and studies.

Generally, we enter into a master service agreement with a CRO under which we execute a separate work order for each preclinical or clinical research project, or we enter into a research and development contract with a CRO for an individual project. Below is a summary of the key terms for CRO engagement:

- **Services.** The CRO provides us with services related to a preclinical or clinical research project as specified in the agreement or a work order.
- **Term.** The CRO is required to complete the preclinical or clinical research project within the prescribed time limit.
- **Payments.** We are required to make payments to the CRO in accordance with the payment schedule agreed to by the parties.
- **Intellectual property rights.** We own all intellectual property rights arising from the preclinical or clinical research project.
- **Risk allocation.** Each party should indemnify the other party for losses caused by its fault or gross negligence. If the research fails due to unresolvable technical difficulties or otherwise due to circumstances beyond a party’s control, the parties should negotiate how to allocate the losses resulting from such failure.

During the Track Record Period, we collaborated with a total of 20 CROs. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, we engaged the services of 15, 14 and 7 CROs, respectively, incurring related research and development expenses of US\$3.0 million, US\$2.4 million and US\$0.7 million for the same periods, respectively. During the Track Record Period, none of our CROs and consultants, including their directors, shareholders and senior management, had any past or present relationship with us or our subsidiaries, shareholders, directors or senior management, or any of their respective associate.

MANUFACTURING

GMP-compliant, Commercial-ready Suzhou Manufacturing Facility

We have established an in-house, commercial-ready gene therapy manufacturing facility, with the ability to scale complex gene therapy production processes while meeting the

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global regulatory and safety standards to support our current clinical trials and commercial production in the future. Our manufacturing facility is located in Suzhou, Jiangsu province, China, occupying approximately 4,000 sq.m. of land, which commenced operations in February 2022. Our Suzhou facility was purpose-built to meet cGMP standards as required by regulatory authorities in the US, EU, and China, enabling global compliance for both clinical and commercial supply of our rAAV gene therapy products.

During the Track Record Period, our manufacturing facility had an aggregate production capacity of 3×10^{18} vg, calculated on the basis of drug substance production at 200L and 500L scales, with capacity to support up to 12 batches per year, including 10 batches at 200L and 2 batches at 500L, applying an upstream expression level of 1×10^{15} vg/L and a downstream purification yield of 40%. After formulation and fill-finish, one batch typically provides approximately 1,200 to 60,000 filled vials (the exact number depends on the program-specific fill volume and output). For more details about our production capacity, please see “— Our Technology Platforms — The AAVANCE™ Manufacturing Platform — Key Features — Large-Scale Production and Significant Cost Advantages.”

During the Track Record Period, we produced (i) 4.4×10^{17} vg of FT-017 at our manufacturing facility calculated based on 2,209 vials produced, each containing 5mL at a concentration of 4×10^{13} vg/mL, and (ii) one batch of FT-003 production, with 3.5 L of drug substance at a concentration of 1.1×10^{13} vg/mL, representing a total viral yield of 3.86×10^{16} vg, representing a utilization rate of approximately 16%. The relatively low utilization rate was primarily due to our production planning being driven by the development stage and clinical demand of our drug candidates. Prior to the Track Record Period, we produced three batches each of FT-002 and FT-003 in 2022 and 2023 to support their IND filings, IITs, Phase I clinical trial and Phase II clinical trial use. As the finished drug products for FT-002 and FT-003 generally have a shelf life of three years, such batches were sufficient to support their clinical trials during the Track Record Period and no additional production of FT-002 was arranged. We produced one batch of FT-003 during the Track Record Period to prepare for its planned Phase III clinical trials, and two batches of FT-017 to support their IND filings and Phase I and Phase II clinical trial use. We currently expect to gradually commence Phase III clinical trial production for FT-002 in the second half of 2026 and 2027.

Our Suzhou manufacturing facility utilizes our AAVANCE™ manufacturing platform, which is based on a Bac/Sf9 system. This platform enables high-yield, scalable, and low-cost production of rAAV vectors, with industry-leading performance in terms of vector genome yield, purity, and potency. See “— Our Technology Platforms — The AAVANCE™ Manufacturing Platform.”

Our Suzhou manufacturing facility is well positioned to support the rapid scale-up and commercial production of our lead gene therapy candidates, including FT-002 and FT-003, as well as other pipeline products. The facility was designed and constructed in accordance with China and U.S. GMP guidance, and the equipment and instruments used at the facility were sourced from leading industry suppliers and are subject to routine maintenance, calibration and validation to maintain good operating condition. We have also established an organizational structure, staffing configuration and quality management system suitable for AAV manufacturing. Our key manufacturing and quality personnel, who joined us primarily before 2022, have remained stable and have accumulated extensive experience in AAV manufacturing and testing. Our quality management system was established with reference to the GMP requirements of the EU, the U.S. and China and covers GMP management throughout the lifecycle of pharmaceutical products, supported by a quality team with extensive GMP compliance management experience and familiarity with China and U.S. GMP requirements. As at the Latest Practicable Date, our manufacturing facility has a maximum annual production capacity of 1.2×10^{18} vg. Based on the foregoing, we believe our current production capacity is sufficient to support the clinical development and initial commercialization for these candidates, taking into account factors such as the estimated addressable patient populations, anticipated market penetration, the competitive landscape, the clinical profiles of the relevant candidates, and the expected timing of regulatory approvals and commercial launch.

Quality Management

Our Suzhou facility is fully integrated with a comprehensive quality management system, supporting end-to-end quality assurance and control throughout the manufacturing

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lifecycle. GMP-compliant operations have enabled us to successfully produce and release 10 clinical and commercial-scale batches with a 100% success rate. The facility’s robust analytical platform supports release testing, stability studies, and regulatory submissions for global markets.

We maintain a comprehensive quality management system which is developed and continuously refined to meet the stringent regulations and guidelines in China and the United States. We closely monitor the evolving cGMP standards and regulatory changes in these key markets, updating our internal procedures accordingly. Our quality management procedures span all key stages of the gene therapy development process.

We carry out our R&D activities in compliance with detailed quality control and quality assurance procedures to comply with relevant regulatory requirements and our internal standards. We conduct rigorous qualifications and selection of raw material suppliers and ensure raw materials are tested and verified before entering the manufacturing process. We provide training for our quality and research and development teams to keep them updated on the latest quality standards and regulatory requirements.

Collaboration with CDMO

In the past, we engaged a CDMO to support our drug development process for FT-001, prior to the commissioning of our Suzhou manufacturing facility in February 2022. This collaboration commenced in June 2021 and the contracted manufacturing concluded in September 2025 when we completed the three-year stability analysis for FT-001. During this period, we entered into service agreements with the CDMO specifying the scope of stability analysis services and relevant quality standards, delivery timelines, and payment terms. We were entitled to conduct on-site audits and inspections to ensure compliance with cGMP and regulatory requirements. Remedies for non-conforming products included replacement of the affected batches and compensation for direct losses. We retained all intellectual property rights related to our products arising from the outsourced manufacturing process.

Since February 2022, following the commissioning of our GMP-compliant Suzhou manufacturing facility, we have established a fully integrated in-house rAAV production system encompassing manufacturing, quality control, quality assurance, and supply chain management. All subsequent production for our drug development has been conducted internally at our own facility.

COMMERCIALIZATION

As of the Latest Practicable Date, we had not obtained marketing approval for any drug candidates, nor had we generated any revenue from product sales.

Anticipating commercialization of our late-stage rAAV gene therapy drug candidates in the next few years, we plan to adopt a flexible commercialization strategy in China. We plan to commence recruitment for a sales and marketing position in 2026; this individual will primarily focus on business development. Based on our current development schedule, we plan to establish an in-house sales team by the end of 2027, and to expand and strengthen the team progressively as products are launched. In some cases we may enhance our in-house sales coverage with capability in specific fields to reach the relevant hospitals, key opinion leaders and patient populations for those products. We are evaluating potential cooperation with external CSOs, large pharmaceutical companies with established sales networks and capabilities, and downstream ophthalmic hospitals.

Our commercialization strategies will be tailored to the characteristics of each product. For products addressing rare diseases, we expect to rely on a combination of our own in-house sales team and relationships with third parties to reach the targeted patient population. We would also consider how to utilize favorable policies, such as within selected industry Pilot Zones in China, such as Hainan province, where certain treatments are allowed before NMPA approval.

For products addressing large-market diseases, particularly in overseas markets, we anticipate seeking commercialization partners with local knowledge and connections in various markets to reach the larger patient pool.

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As disclosed in “Future Plans and Use of [REDACTED]”, we plan to use [REDACTED] of the net [REDACTED], or approximately [REDACTED], to fund preparations for the commercial roll-out of our drug candidates in China, including registrational filings as well as establishing sales and marketing capabilities.

Additionally, we intend to enhance market awareness of gene therapy and our products through active promotions. These may include collaboration with rare diseases foundations or patient associations to host awareness events, partnering with physicians and healthcare institutions to conduct academic symposiums or conferences advocating the necessity and benefits of gene therapy, leveraging real-world data after commercial launch to educate healthcare professionals and patients on the efficacy, safety, and consistency of our products, and utilizing digital tools and engaging data-driven precision marketing service providers for targeted patient outreach. We maintain ongoing communications with ophthalmology experts and principal investigators to conduct market education and prepare for the future commercialization of our product.

We aim to achieve pricing solutions for our patients through active collaboration with payor sides, in particular through negotiating with commercial insurance providers to explore personalized insurance policies that cover rare and chronic disease management.

We seek to avoid cannibalization across our gene therapy pipeline by ensuring each product candidate is deliberately differentiated in indication, target patient segment and intended clinical role. We also apply disciplined portfolio governance to prioritise indications, and adjust, reposition or deprioritise programmes if meaningful overlap emerges, so that candidates are complementary rather than directly substitutable.

SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of (i) CROs who provide third-party contracting services for research and development, (ii) suppliers of equipment and devices for our drug development, (iii) suppliers of office space, laboratory and manufacturing facilities, (iv) SMOs who provide assistance with clinical participant recruitment and (v) professional service providers.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any material disputes with our suppliers, difficulties in the procurement of raw materials or services, disruptions to our operations due to a shortage of or delay in supply of raw materials or services, or significant fluctuations in raw material and/or service prices.

Our purchases from our five largest suppliers in aggregate accounted for 33.1%, 40.8% and 38.3% of our total purchases for the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, respectively. Our purchases from our largest supplier alone accounted for 10.1%, 12.8% and 13.7% of our total purchases for the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, respectively.

Rank	Supplier	Background	Main Products/ Services Provided	Purchase Amount (US\$ in thousand)	Percentage of Total Purchase (%)	Business Relationship Since
For the Year Ended December 31, 2024						
1	Supplier A	A property leasing and management company, based in the United States	Office space and laboratory facilities	1,180	10.1	2021
2	Supplier B	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	986	8.5	2021
3	Supplier C	New drug research and development company, based in China	Preclinical study services for FT-017	771	6.6	2024

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Rank	Supplier	Background	Main Products/ Services Provided	Purchase Amount (US\$ in thousand)	Percentage of Total Purchase (%)	Business Relationship Since
4	Supplier D	A CRO company, based in China	CRO services for FT-002 and FT-003	547	4.7	2024
5	Supplier E	A CRO company, based in the United States	CRO services	372	3.2	2021
Total. . .				3,856	33.1	
For the Year Ended December 31, 2025						
1	Supplier A	A property leasing and management company, based in the United States	Office space and laboratory facilities	1,296	12.8	2021
2	Supplier B	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	792	7.8	2021
3	Supplier F	An international law firm, based in the United States	Legal services	767	7.6	2019
4	Supplier G	A CRO company, based in China	CRO services for FT-002 and FT-003	692	6.8	2023
5	Supplier D	A CRO company, based in China	CRO services for FT-002 and FT-003	590	5.8	2024
Total. . .				4,137	40.8	
For the Six Months Ended June 30, 2026						
1	Supplier B	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	467	13.7	2021
2	Supplier D	A CRO company, based in China	CRO services for FT-002 and FT-003	361	10.6	2024
3	Supplier F	An international law firm, based in the United States	Legal services	228	6.7	2019
4	Supplier H	A SMO company, based in China	SMO services	127	3.7	2022
5	Supplier I	A property leasing and management company, based in the United States	Office space and laboratory facilities	124	3.6	2025
Total. . .				1,307	38.3	

All of our suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, will own more than 5% of our issued share capital immediately after completion of the [REDACTED] has any interest in any of our five largest suppliers in each year during the Track Record Period.

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EMPLOYEES

As of June 30, 2026, we had 54 employees, including 50 in China and 4 in the United States. The following table sets forth the number of our employees by function as of the same date.

Function	Number of Employees
CMC and manufacturing	24
Research and development	18
Management and administrative	12
Total	54

We recruit our employees primarily through online platforms, recruiting websites and headhunter referral. We conduct induction programs and periodic professional training for our employees.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, confidentiality obligations, non-competition clauses, work product and intellectual property assignment clause and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also offer share incentives and promotion opportunities to motivate our employees.

We have not established a labor union. During the Track Record Period and up to the Latest Practicable Date, we did not experience any labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

On July 31, 2025, the PRC Supreme People’s Court promulgated the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) (the “**New Judicial Interpretation**”), which took effect on September 1, 2025. According to the Article 19 of the New Judicial Interpretation, if an employer and an employee agree or the employee undertakes that social insurance contributions need not to be paid, the court shall deem such agreement or undertaking invalid. Where an employer fails to pay social insurance premiums in accordance with the law, and the employee requests to terminate the employment contract and for the employer to pay economic compensation pursuant to Article 38(3) of the PRC Labor Contract Law (《中華人民共和國勞動合同法》), the people’ court shall uphold such requests in accordance with the law. As of the Latest Practicable Date, (i) there were no shortfalls in contribution to social insurance and housing provident funds for our employees; and (ii) no labor disputes or legal proceedings concerning social insurance or housing provident fund contributions had been raised against us. Based on the foregoing, our Directors and our PRC Legal Adviser are of the view that the implementation of the New Judicial Interpretation is not expected to have material adverse impact on our business, results of operations, or financial condition.

INTELLECTUAL PROPERTY

We are committed to the development and protection of our intellectual properties. As of the Latest Practicable Date, our patent portfolio consists of one patent in Japan and 29 patent applications, including seven Patent Cooperation Treaty (“PCT”) patent applications, which typically takes about 5 years to be processed once examination starts, seven U.S. patent applications, five China patent applications (including one Hong Kong patent application), two Canada patent application, three European patent applications, two Japan patent applications, two Australia patent application, and one Korea patent application. Our patent and patent applications primarily include compositions, methods and uses related to our drug candidates and technology platforms. Regarding obtaining granted patents relating to the Core Products, the Directors believe, after consulting the Company’s IP counsel, that granted

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patents are expected to be obtained by the end of 2027 and that material difficulties are not expected beyond those that may be reasonably expected as part of normal patent office examination procedures to obtain granted patents before the expected commercialization of the Core Products.

The patent portfolios for each of our Core Products as of the Latest Practicable Date are summarized below. These patent and patent applications cover material aspects of our Core Products:

- FT-002: We had five patent applications in China, the United States, Europe, and Japan, including one of the patent applications in the United States that received a notice of allowance in May 2026.
- FT-003: We obtained one patent grant in Japan in April 2026. We had seven patent applications in China (including Hong Kong), the United States, Europe, Canada, and Australia, including the patent applications in the United States that received a notice of allowance in June 2026.

These patent applications cover all known key features and/or characteristics of the Core Products. Taking into account the freedom-to-operate searches and analyses we conducted in relation to our Core Products (as discussed below) and the fact that we have not received any material concerns or inquiries from relevant competent authorities relating to the patent applications, we believe that there are no known difficulties or legal impediments to obtain approval for the patents covering the Core Products. For implications if we fail to obtain these patents, see “Risk Factors — Risks Relating to Intellectual Property Rights — If we are unable to obtain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected.”

For more details, please see “Appendix IV — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights — (c) Patents.”

A freedom-to-operate searches and analyses (“**FTO Analysis**”) has been conducted in China and the U.S. in relation to our Core Products.

The key aspect of FT-002 is a viral expression vector comprising codon-optimized nucleic acid sequence encoding RPGR polypeptide for treating X linked retinitis pigmentosa; and the key aspect of FT-003 is a viral expression vector comprising codon-optimized nucleic acid sequence encoding Aflibercept and modified AAV2 capsid with 10 amino acid insertion, for treating age-related macular degeneration.

As such, with respect to the FTO Analysis, searches were focused on whether there are any freedom-to-operate (“**FTO**”) issues on (i) codon-optimized sequences encoding drugs, (ii) inserted amino acid sequences in the AAV2 capsid sequence, and whether there are any broad roadblocks in AAV-based gene therapy to treat disease indications of interest.

In order to evaluate FTO issues on codon-optimized sequences encoding drugs, nucleic acid sequence searches for codon-optimized constructs were conducted. In order to evaluate FTO issues on inserted amino acid sequences in the AAV2 capsid sequence, amino acid sequence search for 10 inserted amino acid sequence was conducted. In order to evaluate FTO issues on the disease treatment itself, searches using disease names as keywords were conducted. No valid claims of third party patents in the U.S. and the PRC that are infringed by FT-002 or FT-003 have been identified.

The Company believes that these searches are sufficient to capture all material aspects of the patent protection relevant to the Core Products.

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Based on the FTO Analysis, our Directors are of the view that there are no valid and enforceable patents of any third party in China and the U.S. covering the amino acid sequences or indications currently under development of our Core Products and we have not infringed any valid and enforceable patents or other IP rights of any third parties.

We have engaged IP counsel to oversee comprehensive planning and development of our intellectual property portfolio, with the objective of mitigating IP-related risks. As of the Latest Practicable Date, we have not received any material concerns or inquiries from relevant competent authorities that lead us to believe that any of the pending patent applications will be finally rejected. In addition, pending applications can protect our IP against third party patent applications filed later than our pending applications.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings in respect of, and we have not received any written notice of, any material claims of infringement or misappropriation of any third party intellectual property rights which may have a material adverse effect on our business, financial condition and results of operations. As of the Latest Practicable Date, we are not aware of any objection or claim from other market players in respect of similar technologies or features underlying their patent applications targeting similar indications which may have a material adverse effect on our business, financial condition and results of operations.

COMPETITION

The biopharmaceutical and gene therapy industries are characterized by rapidly advancing technologies, competition and a strong emphasis on drugs protected by intellectual property rights. We face actual or potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions.

We operate in the gene therapy segment of the biopharmaceutical market that primarily addresses ophthalmic and cardiovascular diseases. There are other companies working to develop therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of the companies we are competing against or with which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our research and development.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various health, work safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with health, work safety and environmental laws and regulations applicable to our operations in all material respects and had not been subject to any material claims, fines or other penalties due to non-compliance with health, work safety or environmental regulations that would materially and adversely affect our business, financial condition or results of operations.

Governance on ESG Matters

We have built a series of policies and procedures to contribute to social, health, work safety and environmental matters. Going forward, it is our objective to proactively identify

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and assess the actual and potential environmental, social and governance (“ESG”) risks that may impact our business, strategy and financial performance, and integrate considerations of ESG issues into our business, strategic and financial planning, in compliance with the recommendations made by the Environmental, Social and Governance Reporting Guide in Appendix C2 to the Listing Rules.

Our Board is responsible for monitoring and enhancing compliance with ESG laws and regulations. Our ESG Review committee regularly reports to the board on ESG matters, and the Board makes decisions regarding our policies and practices in alignment with ESG requirements. The Board will continue to monitor, evaluate, and address ESG issues, overseeing the implementation of policies that promote ESG practices.

Environmental Protection

We strive to conduct our operations in a manner that safeguards the environment associated with our operations.

Wastes

We have established waste management procedures to ensure compliance with relevant waste disposal regulations and to minimize environmental impact. These include maintaining a hazardous waste ledger, completing and executing transfer documentation, and contracting with qualified institutions for hazardous waste disposal.

Greenhouse gas emission

Our greenhouse gas emissions consist of Scope 1, Scope 2 and Scope 3 emissions. In response to the national carbon neutrality target, we are committed to actively reducing the greenhouse gas emissions produced in our operations.

	For the year ended December 31,		For the six months ended June 30,
	2024	2025	2026
Greenhouse gas emissions			
Scope 1 greenhouse gas (tons of CO ₂ equivalent)	–	368.6	–
Scope 2 greenhouse gas (tons of CO ₂ equivalent)	4,524.0	3,444.0	2,408.5
Scope 3 greenhouse gas (tons of CO ₂ equivalent)	351.8	201.8	30.8
Total carbon emission (tons of CO ₂ equivalent).	4,876.0	4,014.0	2,439.3
Total carbon emission intensity (ton per RMB1 million research and development expenses)	32.9	40.0	67.5

To further reduce our greenhouse gas emissions, we plan to implement low-carbon optimizations in laboratory facility maintenance, business travel, and office space selection areas. We target a 1.0% decrease in GHG emission intensity by the end of 2027, compared against the intensity levels in 2025.

Management of Environmental Protection Matters

We conduct environmental impact assessments to monitor emission levels. The following table sets forth the indicators related to our energy consumption and waste production during the Track Record Period.

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	For the year ended December 31,		For the six months ended June 30,
	2024	2025	2026
Energy consumption:			
Electricity (MWh)	3,449.4	2,302.7	1,292.2
Total direct energy (MWh)	1,626.0	848.5	–
Total indirect energy (MWh)	3,449.4	2,302.7	1,292.2
Total energy consumption (MWh).	5,075.4	3,151.2	1,292.2
Energy intensity (MWh per			
RMB1 million research and development expenses). .	34.3	31.4	35.8
Water (tons)	8,648.0	6,358.0	3,875.0
Waste:			
Hazardous waste (tons)	45.0	40.0	15.8

As our business grows and our candidates move closer to commercialization, we anticipate an increase in resource consumption and emissions. Nonetheless, we are dedicated to implementing a variety of measures to optimize resource use and reduce emissions. Simultaneously, we strive to cultivate a corporate culture that prioritizes environmental protection and work closely with our business partners to establish an eco-friendly ecosystem. Our commitment includes enhancing the environmental performance across our entire value chain, which encompasses office operations, supplier selection, laboratory activities, and manufacturing activities. In addition, we have implemented centralized production scheduling to optimize energy efficiency. During non-production hours, air conditioning systems in production areas are turned off to minimize power consumption. We aim to achieve a 1% reduction in energy intensity by the end of 2027, compared to the level in 2025.

Participant Data Protection and Prevention of Data Manipulation

We are committed to the protection of trial participant information in compliance with the applicable laws, regulations and industry standards.

We have designed strict data protection policies to ensure that the collection, use, storage, and processing of clinical data comply with applicable laws and prevalent industry practices, including our detailed data management plan for each clinical project. The collection of personal data is primarily performed by investigators in our clinical trials and operations. Participants enrolled in the clinical trials are anonymized with assigned subject numbers, and any datasets transferred to us are only associated with the subject numbers, not the actual identities of patients. As a result, we have no access to patients’ personally identifiable information, such as their names, identity numbers, phone numbers or home addresses. Furthermore, we require that all internal employees, as well as hospitals and third-party contractors such as CROs involved in our clinical trials adhere to strict confidentiality requirements. We conduct trainings to ensure compliance with these standards, thus reinforcing our dedication to maintaining the highest levels of data security and patient confidentiality. This comprehensive approach not only meets regulatory expectations but also fosters trust among participants and stakeholders involved in our clinical trial process.

During the Track Record Period and up to the Latest Practicable Date, we had complied with all applicable laws and regulations on data privacy and security in all material respects, and our PRC Legal Adviser is of the view that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable PRC laws and regulations in relation to cross border data transfer in all material respects.

Our contracts with R&D employees contain confidentiality clauses, adding an extra layer of security for the confidential information. Additionally, we generally require CROs to keep all documents, data, records, and information provided by us or generated during the contract strictly confidential.

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Manufacturing and Quality Management

We strive to align our manufacturing and quality management practices with ESG standards. We prioritize partnerships with suppliers who demonstrate strong environmental practices in their raw material sourcing and production processes. Meanwhile, we maintain a comprehensive quality management system which is developed and continuously refined to meet the stringent regulations and guidelines in China, the United States, and Europe. See also “— Manufacturing — Quality Management.”

Management of Third-Party Relationships

We maintain strict compliance standards in our third-party engagements through a robust internal policy framework. Our procurement management system establishes clear protocols for supplier interactions, with specific anti-bribery and anti-corruption provisions. For healthcare professionals, we follow detailed guidelines that govern all professional engagements. Our Anti-fraud and Whistleblower Mechanism Policy and Anti-Corruption Policy provide additional safeguards against corruption and bribery, while our third-party contracts incorporate specific compliance requirements.

Work Safety

We strive to provide a safe and healthy working environment for our employees. To achieve this, we have established stringent safety protocols. These protocols are reinforced by regular safety training initiatives that equip our employees with the necessary awareness and technical expertise to perform their duties safely and efficiently. We have specific protocols in place for managing emergency matters. Regular meetings and periodic inspections are conducted to ensure continuous adherence to our safety standards. Through these efforts, we maintain a secure and productive working environment that supports the well-being of our employees and the success of our enterprise. During the Track Record Period and up to the Latest Practicable Date, we did not have any major workplace accidents.

Workplace Diversity

We are dedicated to fostering an inclusive and open workplace that values equality. Our recruitment practices are strictly merit-based, ensuring that all employees are provided with equal opportunities regardless of gender, age, race, religion, or any other social or personal attributes. As of June 30, 2026, we had a total of 54 employees, of whom 35 employees were female, representing around two-thirds of our total employees. We are committed to maintaining a fair and transparent employee management system and continuously strive to enhance the gender and age diversity of our workforce.

Animal Welfare

We typically engage CROs to conduct animal studies, and the CROs we engaged have obtained certification from the Association for Assessment and Accreditation of Laboratory Animal Care. This certification promotes compliance with key regulations regarding animal welfare, including the humane treatment of all animals, the promotion of psychological well-being, access to adequate veterinary care, ethical reviews of research protocols, proper training for personnel involved in animal care, and ongoing compliance monitoring to uphold high standards of animal welfare throughout the research process.

PROPERTIES

We have a presence in Shanghai and Suzhou in China, as well as in Boston in the United States. As of the Latest Practicable Date, we did not own any properties and we leased a number of properties with an aggregate gross floor area of approximately 4,833.5 square meters in Shanghai, Suzhou, and Boston for various functions.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

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Location	Usage	GFA (Square meters)	Expiry Date
Shanghai, China	Office and R&D	569.6	February 28, 2027
Suzhou, China	Office and manufacturing site	3,862.0	May 19, 2027
Suzhou, China	Equipment and facilities room	309.0	January 19, 2028
Watertown, MA, USA	Laboratory	92.9	September 30, 2026

Pursuant to the applicable PRC laws and regulations, property lease agreements in China shall be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, our lease agreements in China had not been registered. See “Risk Factors — Risks Relating to Government Regulations — Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them” for details.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of June 30, 2021. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 38(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our Group’s interests in land or buildings.

INSURANCE

We maintain insurance policies that are required under applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. Our existing insurance policies cover adverse events in our clinical trials, production facilities and equipment, and we have supplementary commercial insurance plans for our senior management and employees. In line with industry practice, we have elected not to maintain certain types of insurances, such as business interruption insurance. We believe our existing insurance coverage is adequate for our present operations and in line with industry practice. See also “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.”

PERMITS, LICENSES AND REGULATORY APPROVALS

During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite permits, licenses, and regulatory approvals the relevant government authorities that are material for our business operations in the PRC. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred for any regulatory approval for our Core Products since its date of issue.

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

Compliance

During the Track Record Period and up to the Latest Practicable Date, we had complied with all relevant laws and regulations applicable to us in all material respects concerning our operations. For more information about the laws and regulations applicable to us, please see “Regulations.”

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RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to our long term development and success. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global biopharmaceutical markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other biopharmaceutical and gene therapy companies.

To address these challenges, we have adopted a consolidated set 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. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- Our Directors/audit committee oversees and manages the overall risks associated with our business operations;
- Our Director, chief executive officer, and chief medical officer, Dr. Xinyan Li, is responsible for (i) formulating and updating our risk management policy and target; (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 feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competences are in place across our company; and (viii) reporting to our audit committee on our material risks; and
- The relevant departments in our Company, including but not limited to the finance department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice.

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 is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant (the “**Internal Control Consultant**”) to perform certain agreed-upon procedures (the “**Internal Control Review**”), in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group’s entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, procurement management, and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in November 2025 and follow up review in December. The main issues identified during the Internal Control Review in relation to the review scope include that information disclosure management policy and related party transaction management policy need to be established according to the latest Listing Rules. We had thereafter adopted the recommended internal control measures and rectified the internal control findings identified. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal control based on the follow up review.

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During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, protection of intellectual property, environmental protection and occupational health and safety.
- We provide various training programs to keep our employees updated of relevant laws, regulations and policies.
- Our Directors, who are responsible for monitoring the corporate governance of our Group, with help from our legal advisers, 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; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.
- We have engaged Alliance Capital Partners Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules.
- We have engaged a PRC law firm to advise us on and keep us abreast with PRC laws and regulations after the [REDACTED].
- We maintain strict anti-corruption policies 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.

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