

BUSINESS

OVERVIEW

We are a clinical-stage gene therapy company pioneering innovative therapies, with an international footprint and 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 potentially global Best-in-Class 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 novel 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 innovative recombinant adeno-associated virus ("**rAAV**") gene therapies. We have developed a differentiated and clinically advanced pipeline with global Best-in-Class potential. 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 have the most clinically advanced Bac/Sf9-based gene therapy pipeline for ophthalmic diseases in China, including the only clinical-stage drug candidate being investigated for XLRP in China and the only intravitreal gene therapy advancing to Phase II clinical trials for DME in China.

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.

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We have built a proprietary rAAV gene therapy R&D platform, EXACTE™, to enable the selection of drug candidates with optimal 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.

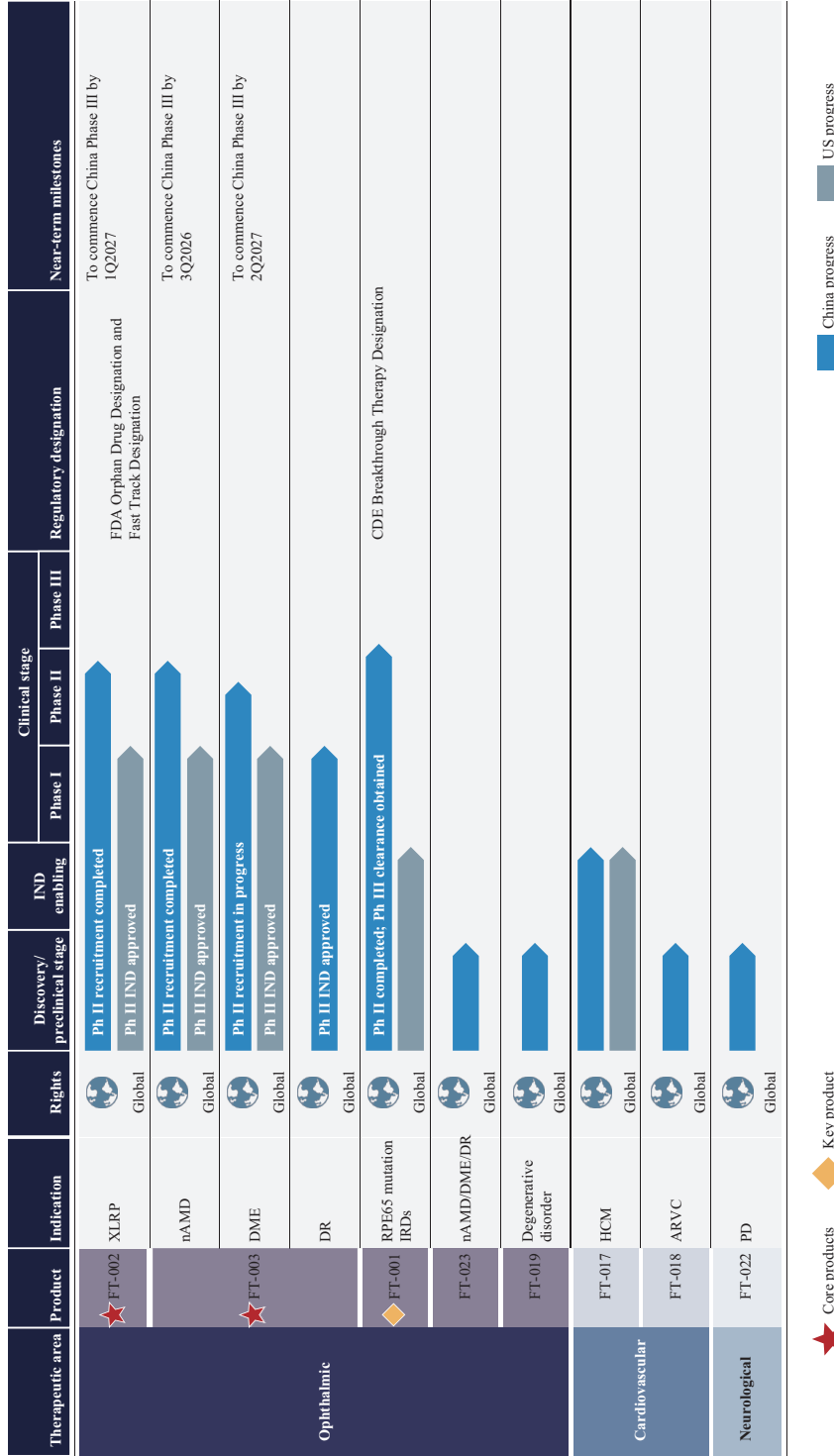
We are the only gene therapy biotech company in China, and one of the few globally, to establish commercial scale Bac/Sf9-based rAAV manufacturing. Our AAVANCE™ manufacturing platform enables cost-efficient, scalable production of our gene therapy products with low empty capsid rate and high product 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 five other preclinical and early-stage gene therapies for the treatment of ophthalmic, cardiovascular and neurological diseases. We have developed all of these therapies in-house based on our own intellectual property 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:



Notes:

- (1) Abbreviations: XLRP = X-linked retinitis pigmentosa; nAMD = neovascular age-related macular degeneration; DME = diabetic macular edema; DR = diabetic retinopathy; RPE65 = retinal pigment epithelium-specific 65 kDa protein; IRD = inherited retinal diseases; HCM = hypertrophic cardiomyopathy; ARVC = arrhythmogenic right ventricular cardiomyopathy; PD = Parkinson's diseases; Ph = Phase; FDA = Food and Drug Administration; CDE = Centre for Drug Evaluation.
- (2) Competent authorities in respective jurisdictions: National Medical Products Administration in China and the Food and Drug Administration in the United States.

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FT-002, a potentially global Best-in-Class rAAV gene therapy for XLRP

Our Core Product FT-002 is a potentially global Best-in-Class novel 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 are conducting 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 two 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.

FT-003, a potentially global Best-in-Class rAAV gene therapy for nAMD and DME

Our Core Product FT-003 is a potentially global Best-in-Class 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. 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 initiated Phase II clinical trials of FT-003 for DME and nAMD in China, where FT-003 is the only intravitreal gene therapy entering Phase II trials for DME and is one of seven entering Phase II trials for nAMD. We have also obtained FDA clearance for Phase II trials in the United States for both nAMD and DME. 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 two and a half years.

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FT-001, an rAAV gene therapy for RPE65m IRD

Our Key Product FT-001 is a novel drug candidate for treating IRD caused by biallelic mutations in the RPE65 gene. It is our most clinically-advanced drug candidate, and its robust clinical results provided early validation for our technology platforms. RPE65m 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 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.

Other drug candidates

Our pipeline also includes two other gene therapy drug candidates in ophthalmic diseases, two in cardiovascular diseases, and one in neurological 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 innovative and effective therapy for retinal vascular leakage disorders other than the anti-VEGF therapy, as it focuses on a novel 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.

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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 supported by robust clinical data with global Best-in-Class potential

Leveraging our proprietary EXACTE™ and AAVANCE™ technology platforms, we have built a differentiated and competitive pipeline with leading positions in terms of clinical advancement in China. We have chosen ophthalmic diseases as our first therapeutic area of concentration due to the localized delivery options, immune-privileged environment, and unmet medical needs. 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 global Best-in-Class potential with 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 potentially global Best-in-Class drug candidate being investigated to treat XLRP. FT-002 has received Orphan Drug Designation and Fast Track Designation in the United States. We are conducting Phase II clinical trials of FT-002 in China and have received clearance from the FDA for Phase II trials in the United States. Currently there are no approved treatments for XLRP globally, indicating significant unmet medical need.
- Our Core Product FT-003 is a drug candidate being investigated for intravitreal treatment of nAMD and DME, with global Best-in-Class potential demonstrated in clinical study. In 2025, there were an estimated 4.2 million nAMD patients and 7.8 million DME patients in China, and an estimated 1.6 million nAMD patients and 2.0 million DME patients in the United States. We have initiated Phase II clinical trials of FT-003 for DME and nAMD in China, where FT-003 is the only intravitreal gene therapy entering Phase II trials for DME and is one of only two entering Phase II trials for nAMD. We have also obtained FDA clearance for Phase II trials in the United States for both nAMD and DME.
- Our Key Product FT-001 is a gene therapy drug candidate for treating IRD caused by biallelic mutations in the RPE65 gene. 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. If approved, FT-001 would be one of the few treatment options for RPE65m IRD in China.

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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.

<u>Category</u>	<u>Bac/Sf9</u>	<u>HEK293</u>	<u>Descriptions</u>
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.
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.

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Category	Bac/Sf9	HEK293	Descriptions
Empty Capsid Rates	Relatively low	Relatively high	The Bac/Sf9 system generally results in lower empty capsid rates. In a head-to-head study in which AAV2.N54-aflibercept vectors were produced in Bac/Sf9 and HEK293 platforms under matched upstream/downstream protocols, 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.
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.

Source: 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 10¹²–10¹⁴ vector genome (“vg”) per litre; in comparison, our bioreactors achieve upstream production yields of more than 10¹⁵ 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 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.

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Strong translational medicine and clinical operation capabilities leveraging strengths across our international footprint

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.

We have constructed an agile and well-coordinated clinical operation. Early-stage innovation and preclinical studies can be seamlessly progressed 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, demonstrating our highly efficient execution capabilities and cross-regional collaboration. Since our inception, we have successfully advanced three drug candidates to Phase II clinical trials.

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

Our proprietary R&D platform, EXACTE™, is a cutting-edge 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, driving superior clinical outcomes and competitive cost structure.

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

- *Capsid engineering:* With our proprietary 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 visionary leaders with rich industry experience and strong scientific expertise in cell and gene therapy, including the research, translational, clinical, and manufacturing aspects of operating an innovative 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 20 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, and she has 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.

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Our committee of expert advisors comprises four distinguished experts in the biopharma and the cell and gene therapy fields: Dr. Philip Reilly, Dr. Robert Kotin, Dr. Arshad M. Khanani and Dr. Xiaorong Li. During his time at the National Institutes of Health ("NIH"), Dr. Kotin's laboratory invented and developed the scalable rAAV production process in Bac/Sf9 cells. His expertise and deep scientific insight helped us develop our own AAVANCE™ manufacturing platform. We have received support from multiple world-class institutional investors to date including OrbiMed, Creacion Ventures, Boyu, and Hongshan.

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 recruitment and dosing for FT-002 in China. We anticipate initiating Phase III by the first 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.

We are advancing FT-003 for both nAMD and DME indications. We have completed Phase II recruitment for nAMD in China and anticipate initiating Phase III by the third quarter of 2026. Meanwhile, we are in the process of recruiting participants for the Phase II trial for DME and we expect to initiate Phase III by the second 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.

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Some examples might include further developing novel 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, cardiovascular and neurological indications. In addition, we aim to leverage our deep 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 a capable sales team and capitalize on collaboration with third parties. We would also consider fast-to-market commercialization on the back of 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 novel 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 our addressable market. We will also evaluate opportunities to collaborate with global pharmaceutical companies to leverage our proprietary platform and expand our portfolio for the global market.

Cultivate and retain world-class talent to transform human capital into the decisive 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 to raise organizational depth. As our clinical drug candidates advance towards approval, we also intend to build a strong in-house sales team to support commercialization needs after market launch.

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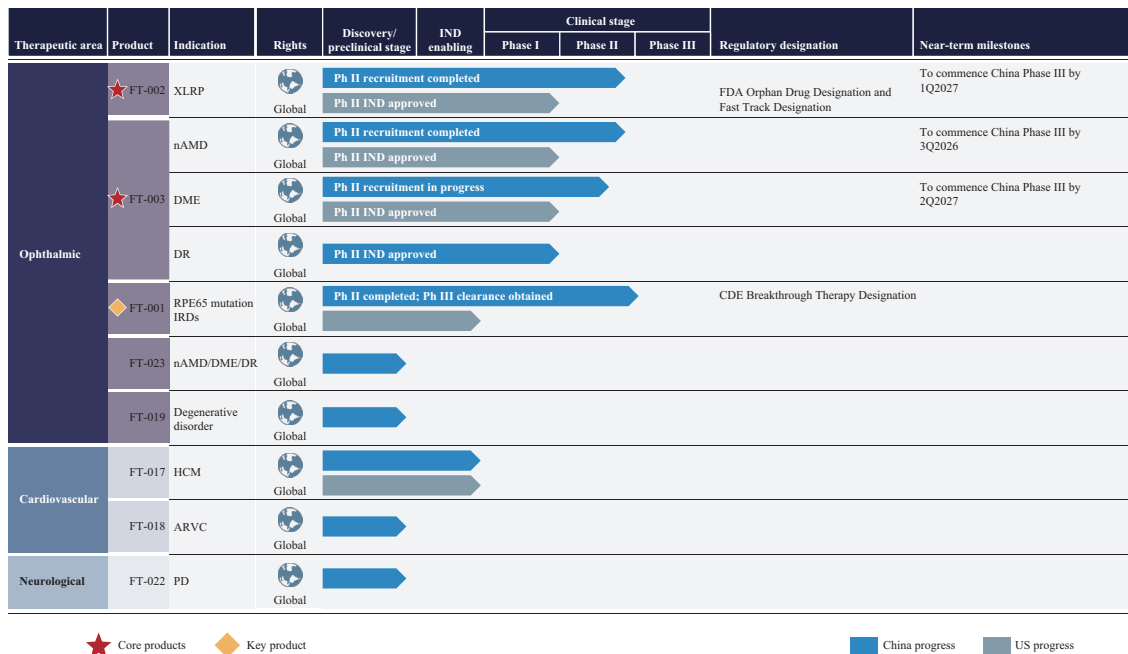
OUR PIPELINE

Pipeline Overview

We have built a differentiated and competitive rAAV gene therapy pipeline with leading positions in terms of clinical advancement by leveraging our proprietary EXACTE™ R&D platform and AAVANCE™ manufacturing platform, executional excellence, and experienced R&D team.

As of the Latest Practicable Date, our product pipeline consisted of eight in-house developed rAAV gene therapy candidates, including (i) two Core Products, namely FT-002, a potentially global Best-in-Class drug candidate being investigated to treat XLRP, and FT-003, a potentially global Best-in-Class 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) five other preclinical and early-stage gene therapy drug candidates for the treatment of ophthalmic, cardiovascular and neurological diseases.

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



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Pipeline Strategies

Our pipeline strategies are designed to address primarily large-market or currently untreatable diseases with innovative, 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.

Gene therapy offers a transformative approach by addressing the underlying genetic causes of disease. rAAV, a small, non-pathogenic viral vector, is the leading platform for *in vivo* gene therapy due to its efficient DNA delivery, low immunogenicity, and minimal integration into the host genome, enhancing safety and efficacy. rAAV vectors are engineered to deliver a functional gene of interest (“GOI”) directly into target tissues, enabling sustained therapeutic protein expression and, in some cases, potentially reverse the progression of disease.

The rapid growth of rAAV gene therapy clinical trials globally, especially in China, highlights its increasing clinical value and emerging role in the global drug market. For large-market diseases requiring lifelong management, rAAV gene therapy offers a compelling alternative — a single treatment with long-term benefits. This reduces the burden of frequent interventions and provides pharmacoeconomic advantages by lowering overall treatment costs and improving quality of life. For currently untreatable inherited diseases, rAAV gene therapies offer hope by correcting underlying genetic defects.

Our rAAV gene therapy pipeline is built on scientific rigor, operational excellence, and a commitment to patient access, with a focus on ophthalmic and cardiovascular diseases with significant unmet needs:

- **Strategic Focus on Large-market or Currently Untreatable Diseases:** Our pipeline addresses large-market or currently untreatable diseases with significant unmet needs, including multiple potentially global Best-in-Class assets supported by clinical data. Specifically, 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 also expanding into cardiovascular diseases and neurological diseases, targeting diseases such as HCM, ARVC and Parkinson’s disease, all of which have significant unmet needs and large market potential.
- **Innovative Approaches:** We aim to develop gene therapies with superior safety, efficacy, and patient convenience at an affordable cost. Our innovation in AAV capsid selection and genetic payload design emphasizes safety and effectiveness. Our pipeline includes two late-stage clinical programs with FT-003, our Core Product for nAMD and DME, positioned as a potentially global Best-in-Class

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therapy. It 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 two years. FT-002, our Core Product for XLRP, is a potentially global Best-in-Class gene therapy. It has demonstrated sustained improvements in visual function, retinal structure, and vision-related quality of life over one year till the latest data cut-off date. FT-002 has been granted Orphan Drug Designation and Fast Track Designation by the FDA. FT-001, our Key Product for RPE65-mediated IRD, has been granted Breakthrough Therapy Designation by the CDE. It has shown marked improvements in functional vision and retinal sensitivity as early as Week 4, with durable benefits observed for nearly two years post-treatment. Supported by robust clinical data, these programs are progressing into late-stage development. FT-003 is expected to begin Phase III trials for nAMD in the third quarter of 2026 in China and for DME in the second quarter of 2027 in China.

- **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 and Product Quality:** Product quality and safety are critical to our product development and manufacturing. Our EXACTE™ R&D platform integrates proprietary 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%. Clinically, FT-002 has demonstrated no dose-limiting toxicity, ocular serious adverse events (“SAEs”), retinal pigment epithelium (“RPE”) atrophy, or macular thinning for up to two years. FT-003 exhibits a comparable safety profile in both nAMD and DME, with efficacy that is superior in nAMD and comparable in DME relative to competitors such as ixo-vec (formerly known as ADVM-022) and 4D-150. These results underscore the effectiveness of our integrated platforms in delivering high-quality and safe gene therapies.

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- **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.

OUR DRUG CANDIDATES

FT-002, a potentially global Best-in-Class rAAV gene therapy for XLRP, our Core Product

Overview

FT-002 is a potentially global Best-in-Class 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.

Developed in-house based on proprietary intellectual property, FT-002 leverages advanced rAAV vector technology to deliver a codon-optimized, full-length RPGR-ORF15 gene, which is essential for normal vision and is commonly mutated in certain inherited retinal diseases such as XLRP, directly to retinal cells, with the aim of expressing the active RPGR protein to rescue the functional and/or structural loss of the photoreceptor cells due to the RPGR gene mutations, which leads to improved visual function and halts disease progression.

We have completed Phase I clinical trials in China in August 2024 and Phase II clinical trials in China are ongoing. 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.

With its innovative design, its robust preclinical and clinical data, and our cost-effective manufacturing platform, we believe FT-002 is well positioned to address this severe, inherited condition which is currently untreatable and deliver transformative value to patients worldwide.

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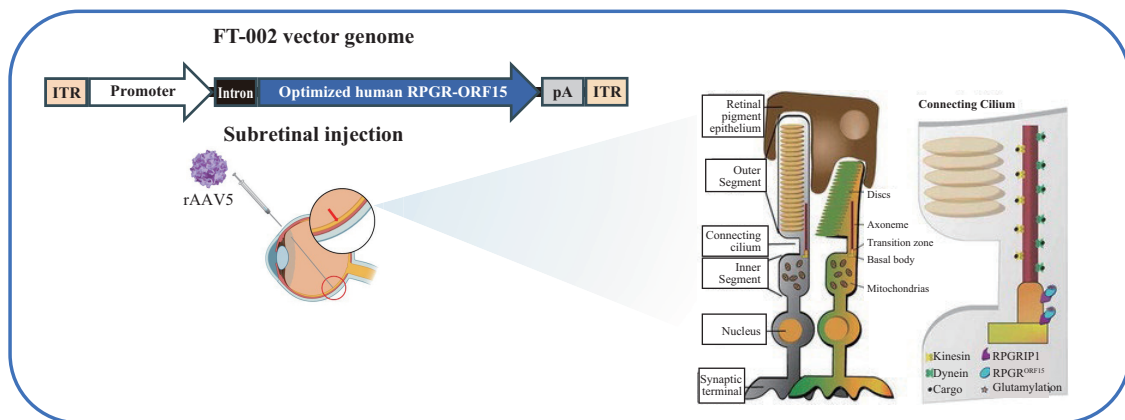
Drug Design and Mechanism of Action

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 and innovative 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.

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



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

Source: Literature Review

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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 *Worldwide Carrier Frequency and Genetic Prevalence of Autosomal Recessive Inherited Retinal Diseases (2020)*, 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 about 62,000 XLRP patients in China and 14,800 XLRP patients in the United States in 2024.

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 status 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, driving continued innovation and patient benefit.

As of the Latest Practicable Date, there are two rAAV gene therapy drug candidates in the process of clinical development for the treatment of XLRP treatment 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	Phase	First Posted Date	Country	Production Platform
Laruparetigene zosaparvovec (laru-zova, AGTC-501)	Beacon Therapeutics	RPGR	Phase II/III	2021-04-20	UK, US, Australia	HSV/BHK
FT-002	Frontera Therapeutics	RPGR	Phase I/II	2024-02-07	China	Bac/Sf9
			Phase II IND Approval	2024-09-23	US	

Note:

- (1) 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.

Source: Frost & Sullivan Report

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Key Advantages

FT-002 represents a pioneering 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. With global Best-in-Class potential, its innovative design, its robust preclinical and clinical data, and our cost-effective manufacturing platform, we believe FT-002 is well positioned to capture significant market share and deliver transformative value to patients with XLRP worldwide.

- **Potentially Global Best-in-Class and Only Clinical-Stage rAAV Gene Therapy for XLRP in China.** We believe FT-002 has global Best-in-Class potential due to its safety, efficacy and cost advantages. It 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.
- **Innovative Drug Design for Superior 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 is meticulously optimized, incorporating a carefully selected promoter, 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 investigator-initiated trials, sustained improvements in visual function were observed in participants who received a single subretinal injection of FT-002, particularly in best corrected visual acuity (“BCVA”) and retinal sensitivity. Some individuals exhibited especially notable increases in retinal sensitivity following treatment, highlighting the potential for significant patient benefit.

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- o In the Phase I clinical trial, adult participants in the high-dose group of FT-002 experienced meaningful gains in both 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 nine 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 more favorable 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 our proprietary Bac/Sf9 system, which enables low empty capsid rates and a highly competitive reduction in production costs, supporting broader patient access and commercial viability.
- **High Probability of Success and Global Commercial Potential.** With its innovative 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 deliver transformative value to patients with XLRP worldwide.

Summary of Clinical Trial Data

Investigator Initiated Trial

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.

Safety data. The IIT data demonstrated that FT-002 was safe and well tolerated. Up to the longest follow-up of two 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.

Efficacy data. The IIT data demonstrated improvements in retinal function and vision-related quality of life, with stable visual acuity.

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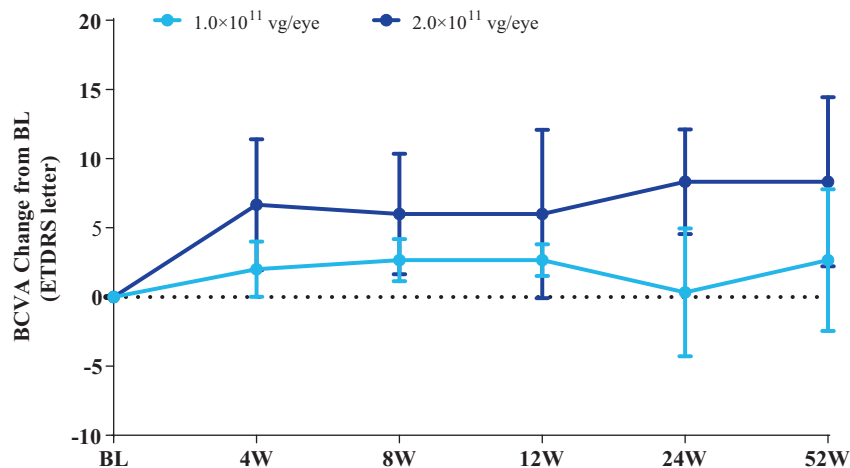
Phase I Clinical Trial

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.

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.

Trial status. The clinical trial was initiated in April 2024 and completed in August 2025.

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 mean BCVA improvement was 8.3 ± 6.11 letters, with 66.7% of participants achieving BCVA gain of more than 5 letters and 33.3% of participants gained more than 15 letters. 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 medium- and high-dose FT-002 experienced sustained improvements in BCVA.



At Week 52, the mean 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, demonstrating the vision-related quality of life of the participants was highly improved.

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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. 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 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. All participants experienced TEAEs related to the surgical procedure including vitritis and iritis.

Ongoing 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 pediatric participants aged 8 to 17 years 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.

Trial objectives. The primary objective was to evaluate the safety, tolerability and efficacy of a single subretinal injection of FT-002 at RP2D in pediatric XLRP participants.

Trial status. This Phase II clinical trial was initiated in February 2025, and completed the enrollment of six pediatric participants in July 2025. As of the Latest Practicable Date, all enrolled participants have completed 12 weeks of follow-up.

Efficacy data. Based on 12-week follow-up data, the study eye of each participant demonstrated a remarkable improvement in LLVA, with an average increase of 7.5 letters from baseline.

Additionally, among four participants assessed by microperimetry at Week 12, the mean retinal sensitivity of the study eye was improved, and three out of these four participants met the microperimetry responder criteria with more than 7 dB improvement at more than 5 loci. Preliminary results from this Phase II clinical study indicate that pediatric participants receiving FT-002 experienced significant improvements in LLVA, with a trend toward improvement in retinal function as measured by microperimetry.

Safety data. Based on 12-week follow-up data, all participants demonstrated good tolerability and safety. No SAEs occurred, and there were no FT-002 related TEAEs observed. Importantly, compared to adult participants, the 6 pediatric participants did not experience any new safety signals. The incidence and severity of FT-002-related adverse events in this age group were comparable to those observed in adults.

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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. 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. We consulted with the CDE, which 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 based on CMC, preclinical, and Phase I clinical data generated in China, according to Frost & Sullivan.

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

We have completed Phase II recruitment and dosing for FT-002 in China. We intend to conduct 52 weeks of follow-up according to the trial design. We anticipate initiating Phase III by the first 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.

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

FT-003, a potentially global Best-in-Class rAAV gene therapy for nAMD and DME, our Core Product

Overview

FT-003 is a potentially global Best-in-Class 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 designed to provide a transformative, long-acting therapeutic solution through a single intravitreal injection. FT-003 leverages a proprietary engineered AAV2 variant capsid (“**rAAV2m**”) that enables efficient and broad transduction of multiple retinal cell types, enabling robust and sustained intraocular expression of aflibercept, thereby inhibiting pathological neovascularization, reducing vascular permeability, and preventing ocular vascular leakage.

FT-003 is administered via a standard intravitreal injection, a widely adopted out-patient procedure that does not require specialized surgical equipment. This approach facilitates broad clinical adoption and patient access, in contrast to subretinal or suprachoroidal delivery.

FT-003 is the only intravitreal gene therapy entering Phase II trials for DME in China, and is the most advanced intravitreal gene therapy entering Phase II trials for nAMD in China, according to Frost & Sullivan. We have developed FT-003 in-house based on our own intellectual property.

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Drug Design and Mechanism of Action

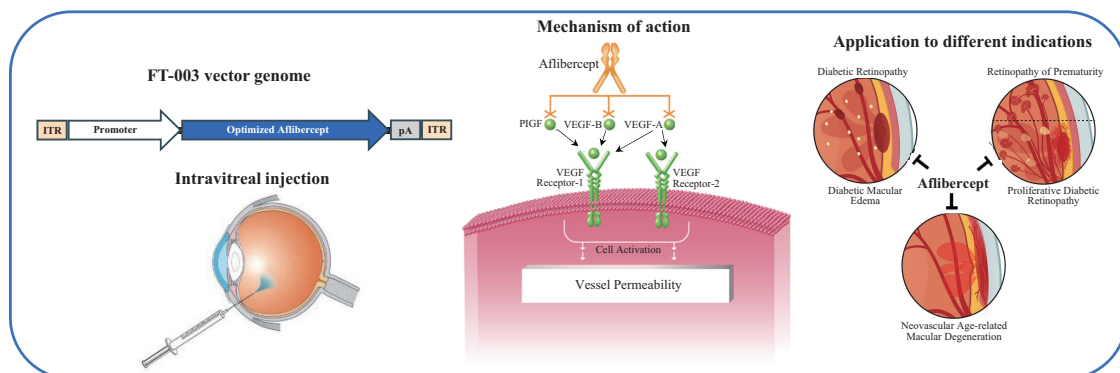
FT-003 utilizes an rAAV2m capsid that is administered via intravitreal injection. Unlike many other rAAV vectors, the rAAV2m capsid in FT-003 is specifically designed to efficiently penetrate the inner limiting membrane of the retina. This targeted vector design enables broad and deep transduction across 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 (“**PIGF**”). 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 PIGF 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 4.1 million nAMD patients and 7.6 million DME patients in China and approximately 1.6 million nAMD patients and 2.0 million DME patients in the United States in 2024. Aside from these two countries, the rest of the world had approximately 15.5 million nAMD patients and 16.5 million DME patients in 2024.

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 innovative 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\$15.6 billion in 2024 and is expected to reach US\$42.2 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 superior durability and reduced treatment burden.

In this competitive landscape, FT-003 is positioned as a potentially global Best-in-Class gene therapy candidate. It is designed to deliver long-term expression of aflibercept via a single intravitreal injection, potentially eliminating the need for frequent repeat dosing. FT-003 is among the most advanced programs globally for intravitreal gene therapy targeting nAMD and DME. Its features — including robust efficacy, favorable safety profile, and highly attractive cost efficiency enabled by proprietary manufacturing technology — differentiate FT-003 from both traditional anti-VEGF therapies and other gene therapy candidates in development.

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As of the Latest Practicable Date, there are 22 rAAV gene therapy drug candidates in clinical stage for the treatment of nAMD. FT-003 is the most advanced intravitreal gene therapy entering Phase II trials for nAMD in China. 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	Phase	First Posted Date	Country
Intravitreal	Ixoberogene soroparvovec (Ixo-vec, ADVM-022)	Eli Lilly / Adverum	VEGF	Phase III	2025/3/4	US
	4D-150	4D Molecular Therapeutics	VEGFA; VEGFB; VEGFC; PLGF	Phase III	2025/3/7	US, Canada
	SKG0106	Skyline Therapeutics	VEGFA	Phase I/II	2023/8/3	China, US
	FT-003	Frontera Therapeutics	VEGF	Phase I/II	2023/8/21	China
				Phase II IND Approval	2024/11/11	US
	XMVA09	Starrygene Therapeutics Company Limited	ANGPT2, VEGF	Phase I/II	2024/4/12	China
	AB1-110	Avirmax Biopharma	VEGF	Phase I/II	2024/8/8	US
	GZ402663	Sanofi	VEGF	Phase I/II	2024/10/28	US
	IVB-103	Innovec Biotherapeutics	Not disclosed	Phase I/II	2024/11/29	China
	EXG202	Hangzhou Jiayin Biotechnology Co., Ltd	ANGPT2, VEGF	Phase I/II	2025/9/18	China
Subretinal	Surabgene lomparvovec (Sura-vec, ABBV-RGX-314)	Abbvie / Regenxbio	AAV8-VEGF	Phase III	2022/6/7	US, UK, Japan, etc.
	LX102	Innostellar Biotherapeutics	VEGF	Phase II	2024/1/9	China
	KH631	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	VEGF	Phase I/II	2023/1/5	China
	JWK001	Chengdu Gene Vector Biotechnology	VEGF	Phase I	2022/12/10	US
	EXG102-031	Hangzhou Jiayin Biotechnology Co., Ltd	ANGPT2, VEGFA, VEGFC	Phase I/II	2023/3/2	China
				Phase I	2023/10/12	China
	NG101	Reyon Pharmaceutical, Neuracle Genetics	VEGF	Phase I	2023/6/6	US
	RRG001	Shanghai Refreshgene Therapeutics	VEGF	Phase I/II	2023/8/9	US, Canada
	RRGT007	Next Generation Gene Therapeutics	VEGF	Phase I/II	2023/11/21	China
	CRG-B191	Shanghai Keruik Pharmaceutical Technology Co., Ltd	CYP4V2	Phase I/II	2025/1/16	China
	HG202	HuidaGene Therapeutics Co., Ltd.	VEGF	Phase I	2025/11/6	China
RG202	HuidaGene Therapeutics Co., Ltd.	VEGF	Phase I	2023/9/4	China	
RLG-2201	Shanghai Regenlead Therapies Co., Ltd.	VEGF	Phase I	2025/3/3	China	
Suprachoroidal	AL-001	Beijing Anlong Biopharmaceutical Co., Ltd	VEGF	Phase II	2025/2/17	China
	KH658	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	VEGF	Phase I/II	2024/6/13	China

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

As of the Latest Practicable Date, FT-003 is the only intravitreal gene therapy entering Phase II trials for DME in China. 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	Phase	First Posted Date	Country
Intravitreal	4D-150	4D Molecular Therapeutics	VEGFA, VEGFB, VEGFC, PLGF	Phase II	2023-07-05	US, Puerto Rico
	FT-003	Frontera Therapeutics	VEGF	Phase I/II	2023-10-27	China
				Phase II IND Approval	2024-12-25	US
	SKG0106	Skyline Therapeutics	VEGFA	Phase I	2024-01-25	China
Suprachoroidal	Surabgene lomparvovec (Sura-vec, ABBV-RGX-314)	Abbvie / Regenxbio	VEGF	Phase II	2025-04-16	US

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

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Key Advantages

Leveraging an engineered capsid and an optimized gene cassette developed through our EXACTE™ R&D platform and our scalable and cost-efficient AAVANCE™ manufacturing platform, FT-003 is positioned to deliver long-term therapeutic benefit through a single intravitreal injection. FT-003 combines validated molecular targeting, innovative vector and gene design, robust and durable clinical efficacy, a favorable safety profile, and industry-leading manufacturing efficiency. These advantages support its potential to become a potentially global Best-in-Class rAAV gene therapy for nAMD and DME.

- **Global Best-in-Class Potential with Long-Term Disease Control, Significant Reduction in Treatment Burden, and Favorable Safety Profile.** Clinical data from both the IIT study and Phase I clinical trial demonstrate that FT-003 has a more potent efficacy profile and a more favorable 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). A single administration of FT-003 provides sustained improvements in BCVA and CST for up to one year and beyond. All the participants with nAMD and DME significantly reduced the anti-VEGF injection frequency, with the mean annualized anti-VEGF injection rate reduced by 81.9% and 73.4% at the 52-week follow-up. Through 52 weeks, 60.0% of nAMD participants and 33.3% of DME participants were injection-free of supplemental anti-VEGF.

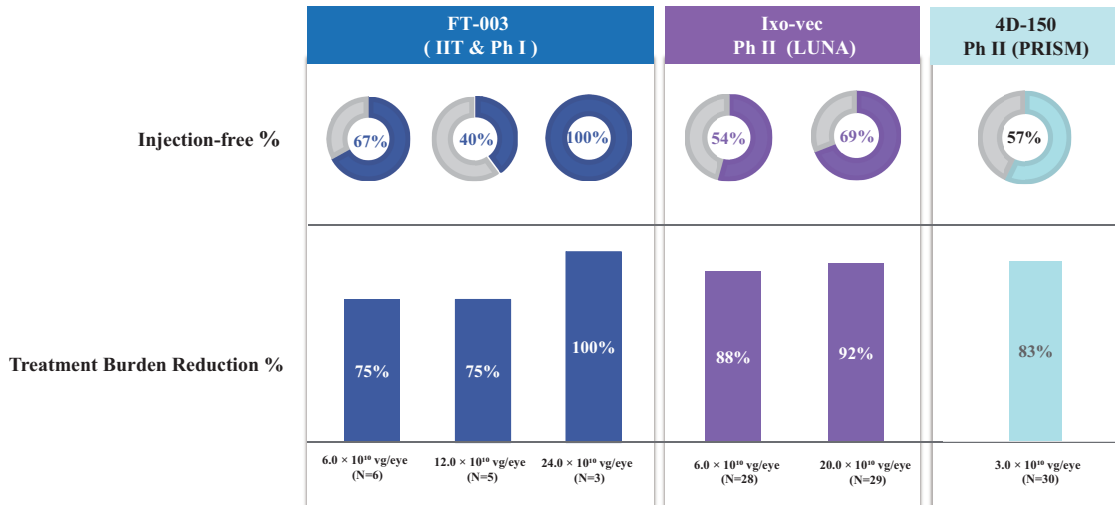
Across all tested dose levels in clinical studies, FT-003 has demonstrated a favorable safety profile. No DLTs or SAEs related to FT-003 have been reported in clinical trials to date, and no new or unexpected safety risks have been identified. Trace to mild intraocular inflammation was observed in some participants with nAMD and DME, with the main manifestation being anterior chamber cells and/or vitreous cells. All cases were effectively managed with standard steroid treatment and did not result in serious complications.

nAMD

- o FT-003 has demonstrated sustained improvements in both BCVA and CST through 52 weeks after administration, exceeding the performance of notable gene therapy candidates such as ixo-vec and 4D-150 based on a non-head-to-head comparison. In the IIT study, two participants (including one treatment-naïve) who received a low dose remained free of anti-VEGF injections for up to 2 years, with significant and sustained improvement in BCVA (22 letters) and reduction in CST (-172 μm). The treatment-naïve participant underwent aqueous humor sampling, which revealed total aflibercept concentrations of 79.3, 54.5, and 55.6 ng/ml at 1, 1.5, and 2 years post-injection, respectively. These sustained levels of aflibercept indicate that FT-003 can provide long-term intraocular expression of the therapeutic protein, potentially reducing or eliminating the need for frequent anti-VEGF injections. In the Phase I clinical trial, a single intravitreal injection of high-dose FT-003 resulted in a mean BCVA increase of 8 letters and a mean CST reduction of 173 μm at Week 52, with all participants remaining free of anti-VEGF injections.

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- o The annualized rate of anti-VEGF rescue injections was reduced by 91% in the IIT study and 79% in the Phase I clinical trial, with 7 out of 11 participants (63.6%) in the Phase I trial requiring no additional injections during the entire year. FT-003 achieved high rates of injection-free status and significant reduction in supplemental anti-VEGF use and treatment burden.



Source: Company Data, Literature Review

- o Our IIT study and Phase I clinical trial indicated that FT-003 demonstrated a more potent efficacy profile and a more favorable 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 (IIT & Phase I)	Ixo-vec (Phase II LUNA)	4D-150 (Phase II PRISM)
Mean BCVA change from BL at Week 52 (ETDRS letters)	+10.0 (6.0 × 10 ¹⁰ vg/eye, N=6) -1.2 (12.0 × 10 ¹⁰ vg/eye, N=5) +8.0 (24.0 × 10 ¹⁰ vg/eye, N=3)	-2.1 (6.0 × 10 ¹⁰ vg/eye, N=29) -1.8 (2.0 × 10 ¹¹ vg/eye, N=29)	+2.2 (3.0 × 10 ¹⁰ vg/eye, N=30)
Mean CST change from BL at Week 52 (µm)	-83 (6.0 × 10 ¹⁰ vg/eye, N=6) -101 (12.0 × 10 ¹⁰ vg/eye, N=5) -180 (24.0 × 10 ¹⁰ vg/eye, N=3)	-10 (6.0 × 10 ¹⁰ vg/eye, N=30) -22 (2.0 × 10 ¹¹ vg/eye, N=30)	-11 (3.0 × 10 ¹⁰ vg/eye, N=30)

Source: Company Data, Literature Review

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DME

- o In the IIT study and Phase I clinical trial for DME, FT-003 demonstrated sustained improvements in both BCVA and CST through 52 weeks post-administration. In the Phase I clinical trial, 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.
- o The need for anti-VEGF therapy was reduced by 86% in the IIT study and 67% in the Phase I clinical trial, with two out of three IIT participants and 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 demonstrated a more favorable safety profile, with no intraocular inflammation (AC or VC \geq 1+) or hypotony events observed through 52 weeks post-administration.
- o In the IIT study and Phase I clinical trial, FT-003 exhibited 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 \times 10 ¹⁰ vg/eye, N=3) +7.3 (24.0 \times 10 ¹⁰ vg/eye, N=3) +11.7 (12.0 \times 10 ¹⁰ vg/eye, N=3) +7.3 (24.0 \times 10 ¹⁰ vg/eye, N=3)	+9.2 (5.0 \times 10 ⁹ vg/eye & 1.0 \times 10 ¹⁰ vg/eye, N=11) +6.4 (3.0 \times 10 ¹⁰ vg/eye, N=9)
Mean CST change from baseline at Week 52 (μm)	-170 (2.0 \times 10 ¹⁰ vg/eye, N=3) -225 (6.0 \times 10 ¹⁰ vg/eye, N=3) -214 (12.0 \times 10 ¹⁰ vg/eye, N=3) -192 (24.0 \times 10 ¹⁰ vg/eye, N=3)	-140 (5.0 \times 10 ⁹ vg/eye & 1.0 \times 10 ¹⁰ vg/eye, N=11) +131 (3.0 \times 10 ¹⁰ vg/eye, N=9)

Source: Company Data, Literature Review

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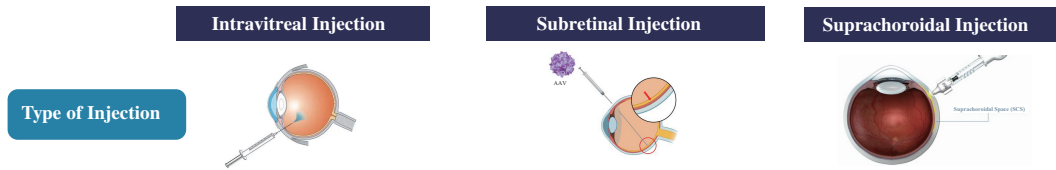
- **One-Time, Long-Acting Therapy with Attractive Commercial and Patient Value**
Proposition: By offering a single-administration, long-acting solution, FT-003 has the potential to transform the standard of care for nAMD and DME, improving patient quality of life and reducing the overall burden on healthcare 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.

Compared to subretinal injection — which requires a specialized surgical procedure often performed in an operating room — intravitreal injection is significantly less invasive and carries a lower risk of serious complications. The technical demands of subretinal delivery, including the need for precise placement and the risk of medication leakage from the retinal incision, further limit its practicality and scalability in routine clinical practice.

Suprachoroidal injection, another alternative, offers broad circumferential coverage and bypasses some inner ocular barriers, but it also presents unique challenges. It requires specialized equipment for accurate delivery. Additionally, achieving therapeutic efficacy with suprachoroidal injection often necessitates the administration of larger doses (5-fold or higher) compared to intravitreal injection. Another challenge is the difficulty in controlling the effectiveness of the therapy, as the suprachoroidal space is outside the blood-retinal barrier, which can lead to increased immune exposure and rapid clearance of therapeutic agents. These factors limit the practicality and predictability of suprachoroidal injection in routine clinical practice.

In contrast, intravitreal injection is not only safer and more convenient but also associated with fewer postoperative complications. It primarily targets ganglion cells and Müller glial cells, which are readily accessible from the vitreous cavity, making it an effective and efficient route for ocular gene therapy. The technical simplicity, safety profile, and broad applicability of intravitreal injection collectively position it as the preferred method for gene therapy delivery in the eye, especially in widespread clinical use where patient safety is paramount.

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Source: Frost & Sullivan Report

- **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

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.

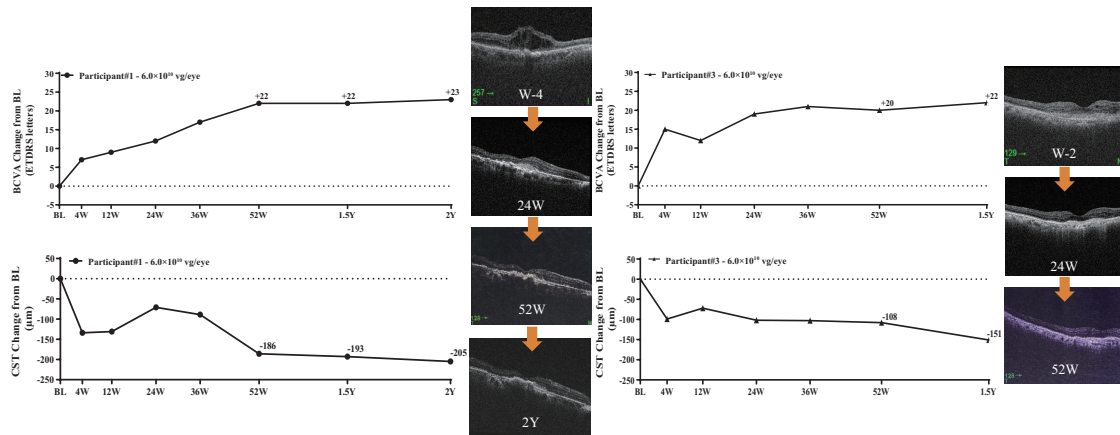
Trial objectives. The primary objective was to evaluate the safety, tolerability, and preliminary efficacy of FT-003 administered via intravitreal injection in participants with nAMD.

Trial status. The IIT study was initiated in December 2022 and completed its two-year follow-up in May 2025.

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 notable improvements in BCVA and reductions in CST over a two-year follow-up period.

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Notably, in the low-dose group, two participants who received FT-003 maintained stable and improved BCVA over two 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 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 × 10¹⁰ vg/eye, which enrolled three participants; (ii) medium dose group: 12.0 × 10¹⁰ vg/eye, which enrolled four participants; and (iii) high dose group: 24.0 × 10¹⁰ vg/eye, which enrolled four participants.

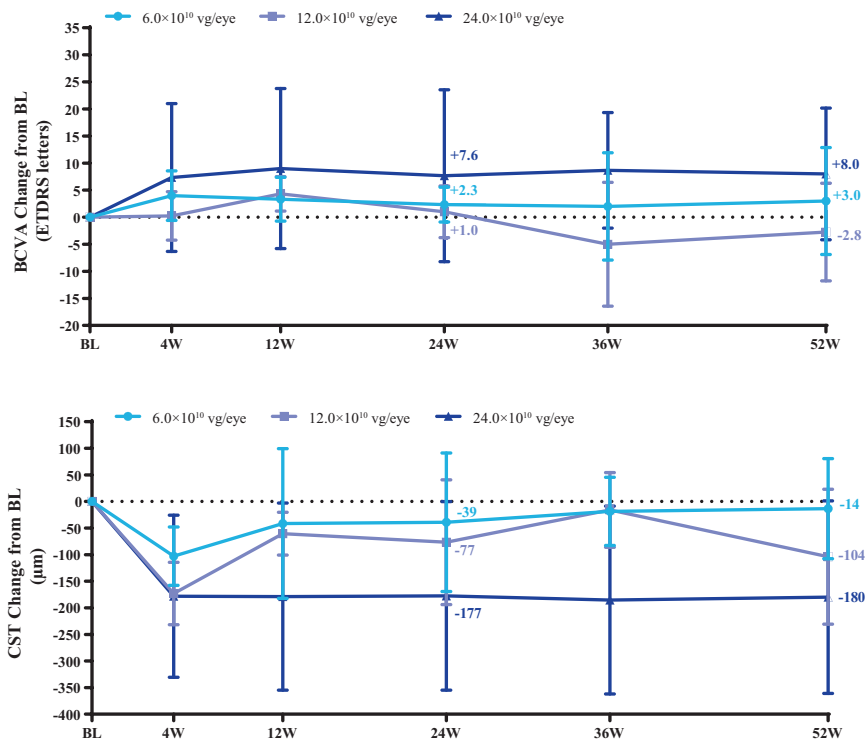
Trial objectives. The primary objectives were to evaluate the safety, tolerability and efficacy of a single intravitreal injection of FT-003 in nAMD patients.

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Trial status. The clinical trial was initiated in August 2023, and completed in August 2024.

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.

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. These results indicate that FT-003 can provide sustained improvements in both visual function and retinal structure.



Source: Company Data

Among all the participants, the annualized anti-VEGF injection rate was reduced by 79%. 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. 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.

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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. 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.

Ongoing Phase II Clinical Trial

Trial design. The dose expansion Phase II clinical trial was a randomized, aflibercept positive control, single-blind, multicenter study. 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 61 participants has been enrolled into these three groups, with low dose, high dose and aflibercept groups comprising 20, 19 and 22 participants, respectively.

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.

Trial status. This Phase II clinical trial was initiated in October 2024, and completed the participants enrollment in July 2025. As of the Latest Practicable Date, all enrolled participants have completed 20 weeks of follow-up.

Summary of Clinical Trial Data for DME

Investigator Initiated Trial

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.

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 notable improvements in BCVA and reductions in CST over two years. Notably, one participant demonstrated a continuous improvement in BCVA, with a gain of more than 10 letters at Week 52 post-administration. In addition, this participant experienced a reduction in CST of more than 300 μ m, indicating a significant decrease in retinal edema and improvement in retinal structure.

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Importantly, the average annualized rate of anti-VEGF injections among these participants decreased by 86% compared to the pre-treatment period. In particular, 67% of participants did not require any rescue therapy with aflibercept throughout the entire 52-week of follow-up, 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.

Trial objectives. The primary objective of this Phase I clinical trial was to evaluate the safety, tolerability and efficacy of FT-003 over 52-week period following a single intravitreal injection in DME patients.

Trial status. The Phase I clinical trial was initiated in December 2023 and completed in October 2024.

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.

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 μ m across three dose groups at Week 52.

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.

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

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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 51 participants have been enrolled as of the Latest Practicable Date.

Trial objectives. The primary objective of this Phase II clinical trial is to evaluate the efficacy and safety of FT-003 in improving visual function, as measured by the change from BCVA and CST following a single intravitreal injection in DME patients.

Trial status. This Phase II clinical trial was initiated in November 2024. As of the Latest Practicable Date, the participants' enrollment is ongoing.

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. 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. 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. We consulted with the CDE, which 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, each based on CMC, preclinical, and clinical data obtained in clinical trials in China.

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.

To date, the NMPA and the FDA have not raised any objections or material concerns with respect to the development of FT-003.

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We are advancing FT-003 for both nAMD and DME indications. We have completed Phase II recruitment and dosing for nAMD in China. We anticipate initiating the Phase III clinical trial for nAMD in China by the third quarter of 2026. Meanwhile, we are in the process of recruiting participants for the Phase II trial for DME in China and expect to initiate the Phase III clinical trial in China by the second quarter of 2027.

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

FT-001, a rAAV gene therapy for RPE65m IRDs, our Key Product

Overview

FT-001 is an innovative 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-mediated IRD approved in the United States and Europe, and no gene therapy option has been approved in China.

Developed by us in-house, FT-001 utilizes wild-type AAV2 capsid to deliver the codon-optimized and CpG-reduced RPE65 gene, equipped with an enhanced promoter/intron system for high and durable transgene expression. In addition, it can be manufactured with an exceptional empty capsid rate below 1%, enabling its safety profile while achieving a reduction of as much as 90% in direct production cost, by our estimate, as compared with the only gene therapy treatment option approved in the United States and Europe for the target disease of FT-001.

FT-001 is our most clinically-advanced drug candidate, 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

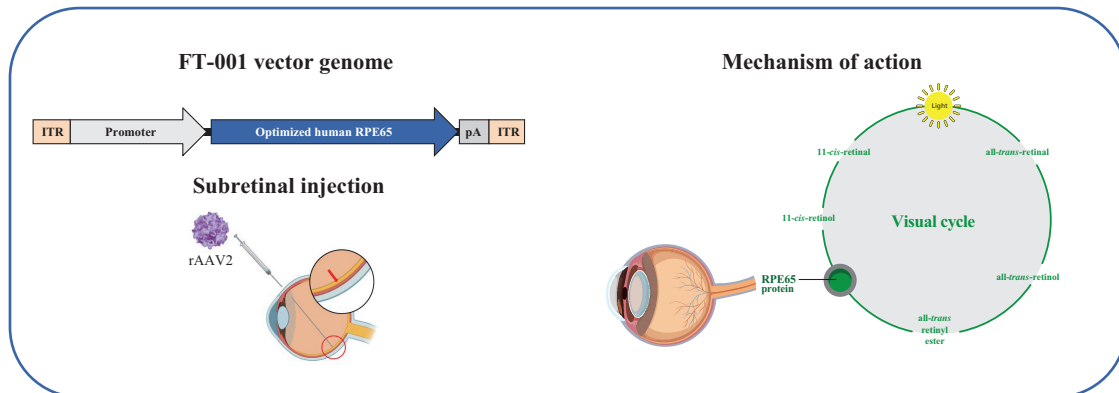
Visual perception results from the biological conversion of light energy to electrical signaling by retinal photoreceptors in the eye. This biochemical process requires the consumption and regeneration of 11-cis-retinal, a derivative of Vitamin A, as a part of the visual cycle. One of the enzymes involved 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

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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.

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-mediated 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-mediated IRDs cause progressive vision loss that begins with night blindness in childhood and typically advances to complete blindness by early adulthood. In China, there are approximately 6.7 thousand RPE65-mediated LCA2 and RP patients in 2024.

The current treatment landscape for RPE65-mediated 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 potentially global Best-in-Class candidate to address this critical gap. Building upon the proven mechanism of action established by Luxturna[®], FT-001 incorporates several key innovations including a proprietary manufacturing process that significantly reduces production costs. This breakthrough would significantly enhance treatment accessibility and commercial viability.

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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	Target	First Approved Date	Country	Route of Administration	Strength	Treatment Cost (US\$ in millions)	Annual Sales in 2024 (US\$ in millions)
LUXTURNA®	Voretigene neparovvec	Roche	RPE65	2017-12-19	US	Subretinal	0.5 ml	0.9	20.4
				2018-11-22	Europe				
				2023-06-01	Japan				

Source: Frost & Sullivan Report

Drugs under Development

Route of Administration	Drug Name	Company	Target	Phase	First Posted Date	Country
Subretinal	LX101	Innostellar Biotherapeutics	RPE65	Phase III	2024-10-10	China
	Cevaretigene ritoparvovec	MeiraGTX	RPE65	Phase I/II	2016-05-24	US, UK
	FT-001	Frontera Therapeutics	RPE65	Phase I/II	2022-11-07	China
				Phase I IND Approval	2022-07-19	US
	HG-004	HuidaGene Therapeutics Co., Ltd.	RPE65	Phase I/II	2023-06-18	China, US

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

Key Advantages

FT-001 has exhibited global Best-in-Class 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 proprietary codon-optimized and CpG-reduced human RPE65 gene and an optimized promotor and intron working in concert to drive robust, high-level and sustained transgene expression. Results from Phase I/II clinical trials demonstrate that, following FT-001 treatment, participants experienced significant and sustained improvements in both visual function and retinal sensitivity, regardless of whether the therapy was administered to one or both eyes. These improvements were maintained over the long term, highlighting the durable efficacy of FT-001.
- Comparable or Superior Efficacy to Existing Therapy with Global Best-in-Class Potential.** In Phase I/II clinical trials, FT-001 exhibited clinical benefits that are comparable to, and in some aspects may be superior 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.

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- Significantly Improved Accessibility.** Due to our proprietary, 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 III Clinical Trial

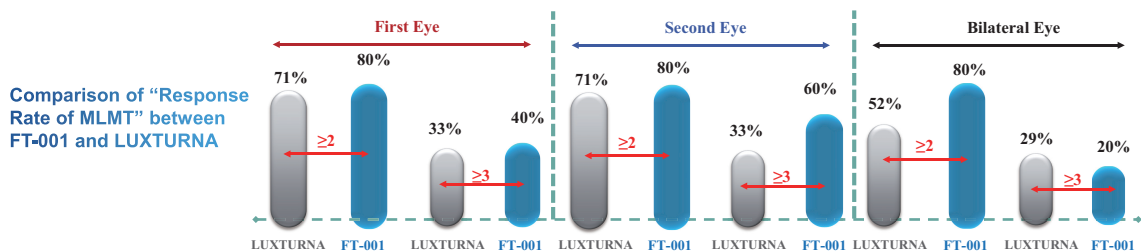
Trial design. The Phase I/II clinical trial of FT-001 was an open-label, dose-escalation and dose-expansion study conducted in participants aged 8 to 45 years with biallelic RPE65 mediated IRD. In the Phase I trial, three dose cohorts were established: (i) low-dose group: 1.5×10^{10} vg/eye, (ii) medium-dose 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. 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. 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.

Trial objectives. The primary objectives were to evaluate the safety, tolerability, and preliminary efficacy of FT-001.

Trial status. The clinical trial was initiated in January 2023, and we completed Phase II in February 2025.

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

The following diagram provides a non-head-to-head comparison between 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 (“MLMT”) at Week 52.



Source: Company Data, Literature Review

BUSINESS

Safety data. The results of the Phase I/II clinical trial demonstrate a favorable safety and tolerability profile of FT-001. No DLTs were observed. Major 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 retinal detachments, RPE atrophy or pigmentation was reported in all participants through the long-term follow-up.

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 expect to consider business development opportunities to facilitate the roll-out of FT-001 going forward. We may also consider fast-to-market commercialization on the back of 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 Candidates for Ophthalmic Diseases

FT-023

FT-023 is a gene therapy candidate in the preclinical stage for treating nAMD, DME and DR. FT-023 focuses on a novel therapeutic target on disease mechanism which is designed to be an innovative and effective therapy for retinal vascular leakage disorders other than the anti-VEGF therapy. When combined with the anti-VEGF pathway, FT-023 is expected to have broader and more sustained efficacy on nAMD and DME patients.

FT-019

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

Other Candidates for Cardiovascular Diseases

Cardiovascular diseases are the leading cause of death globally, many of which stem from genetic defects in certain genes. Traditional drugs mainly focus on reducing symptoms rather than addressing the root causes. Gene therapies offer a way to correct or modify disease pathophysiological mechanism at its source. 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.

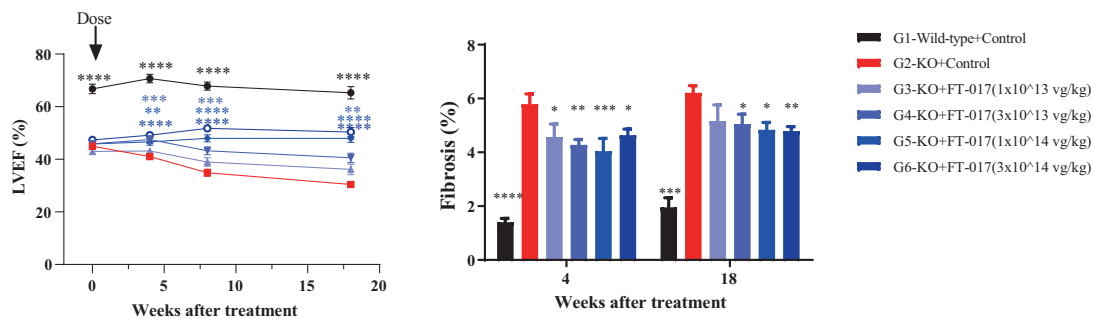
BUSINESS

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 an estimated 17.5 million patients worldwide, including 3 million in China in 2024. Among HCM patients, HCM caused by mutations in the MYBPC3 gene is recognized as one of the most common genetic causes of HCM, with an estimated 7.5 million patients worldwide, including approximately 1.2 million in China in 2024. 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 achieves robust and durable expression of cMyBP-C protein in the heart, leading to significant 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 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 ± 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

BUSINESS

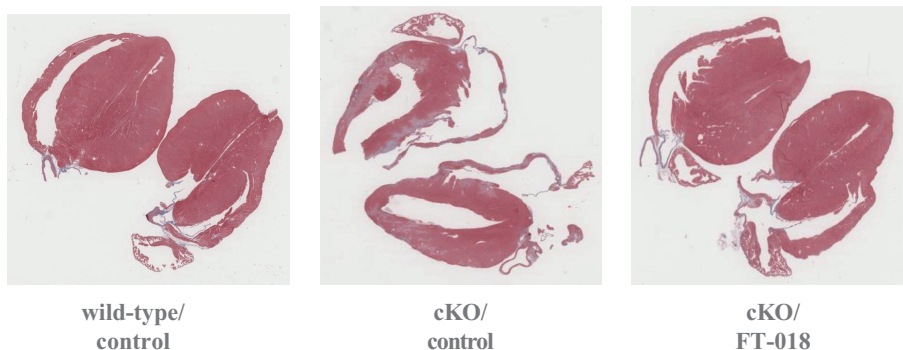
FT-017 has achieved key regulatory milestones, having received IND clearance from both the NMPA and the FDA in April 2025. It is the first rAAV gene therapy for MYBPC3-mutant HCM to enter clinical trials in China, positioning FT-017 at the forefront of innovation in the field of genetic cardiomyopathies.

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 an estimated 2.2 million patients worldwide in 2024, including over 0.36 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 719.7 thousand patients with ARVC caused by mutations in the PKP2 gene worldwide in 2024, including over 140.3 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 leads to significant 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 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

BUSINESS

FT-018's innovative vector design and compelling preclinical efficacy and safety data support its potential as a global Best-in-Class 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 Candidate for Neurological Diseases

FT-022

FT-022 is designed to address 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. If successful, it has the potential to deliver durable therapeutic benefits and establish a potentially global Best-in-Class profile in a major neurological indication.

In addition to our drug candidates for the treatment of ophthalmic, cardiovascular and neurological diseases, we are leveraging the proven versatility of our integrated EXACTE™ R&D and AAVANCE™ manufacturing platforms to explore the development of hematological drug candidates, 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.

OUR TECHNOLOGY PLATFORMS

The EXACTE™ R&D Platform

Overview

EXACTE™ is our proprietary, rAAV gene therapy R&D platform, designed to drive innovation, efficiency, and safety in the creation of transformative gene therapies. EXACTE™ integrates advanced technologies and methodologies from vector design and engineering to candidate selection and preclinical validation. By leveraging EXACTE™, we are able to accelerate the development of gene therapies with enhanced tissue targeting, robust and durable transgene expression, and a favorable safety profile, while maintaining a highly competitive cost structure.

Key Features

Through our EXACTE™ R&D platform, we are able to efficiently generate innovative, safe, and high-quality gene therapy candidates with superior efficacy, safety, and manufacturability. EXACTE™ underpins our pipeline expansion strategy and supports our mission to deliver transformative and accessible gene therapies to patients worldwide.

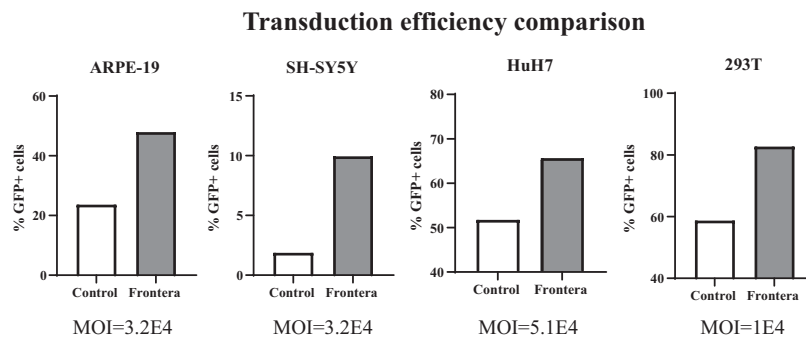
BUSINESS

Capsid Engineering

EXACTE™ employs a rational design and mutagenesis approach to engineer proprietary 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 proprietary baculovirus rep/cap vector design, which is specifically designed for compatibility with our Bac/Sf9-based AAVANCE™ manufacturing platform. This proprietary design enables the production of rAAV vectors with higher biological activity and improved particle integrity.

The optimized design of baculovirus rep/cap vectors achieved through EXACTE™ have led to significant improvements in the production and functional quality of rAAV vectors using the Bac/Sf9-based rAAV gene therapy production infrastructure. Specifically, the optimized 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 superior performance of the optimized AAV2 vectors compared to those produced with the control design.



Source: Company Data

BUSINESS

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.
- **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 optimizations 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.

BUSINESS

The AAVANCE™ Manufacturing Platform

Overview

We have built the proprietary 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.

Two of the greatest challenges in the gene therapy industry are safety and cost. We believe that our AAVANCE™ manufacturing platform addresses these challenges. The AAVANCE™ platform is a cornerstone of our strategy to provide innovative and affordable gene therapies to patients globally, supporting our rapid pipeline advancement and meeting both clinical and commercial demand.

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 Features

Versatility and Safety

We have developed a proprietary, 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.

BUSINESS

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 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 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 science-based biotech company focused on utilizing our EXACTE™ R&D platform and our AAVANCE™ manufacturing platform to develop novel rAAV gene therapies. We believe research and CMC development is critical to our future growth and our ability to remain competitive in the global gene therapy market. We are dedicated to building an innovative rAAV gene therapy pipeline that covers ophthalmic, cardiovascular, and neurological therapeutic areas by leveraging our in-house research and development capabilities, which span internal discovery, preclinical research, translational medicine, clinical development, CMC, and regulatory affairs.

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We have constructed an agile and well-coordinated R&D team. Early-stage innovation and preclinical studies can be seamlessly progressed into clinical trials with minimal delays. In collaboration 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 lead identification to IND approval, demonstrating our highly efficient execution capabilities and cross-regional collaboration.

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

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 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 September 30, 2025, our in-house R&D team consisted of 37 members across China and the United States, over 54% 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 nine years. We place a strong emphasis on academic qualifications, industry experience, and complementary expertise when building our R&D team, which has allowed us to assemble strong talent that can effectively leverage their accumulated expertise across all aspects of gene therapy drug R&D.

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 innovative 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.

BUSINESS

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 12 years of experience at leading biotechnology companies. Our clinical operations function is led by senior director Mr. Minghui Xue, who brings 15 years of experience from several industry-leading biotech companies. Our CMC function is led by the head of manufacturing, Mr. Peng Yang, who has 16 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 15 years of experience at leading biotechnology companies and research institutions.

During the Track Record Period and up to the Latest Practicable Date, substantially all key R&D personnel involved in the research and development of our Core Products, FT-002 and FT-003, remained employed by us.

R&D Centers

We have developed an end-to-end integrated operational system combining scientific insights with executional excellence to achieve efficient pipeline progression. 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.

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. Our R&D process is designed to ensure scientific rigor, innovation, and strategic alignment at every stage.

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 proprietary 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.

BUSINESS

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 innovative 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 support.** Our CMC team produces material for preclinical and IND-enabling studies, and is responsible for producing CMC-related regulatory documentation.

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- **Clinical support.** For ongoing clinical trials, our CMC team manages clinical trial material supply working cross-functionally with the internal clinical and regulatory teams as well as external supply.
- **Commercial manufacturing.** Our CMC team will lead the manufacturing process in the future for commercial manufacturing at our GMP-compliant Suzhou manufacturing facility.

Our proprietary AAVANCE™ manufacturing platform utilizes a Bac/Sf9 system, enabling high-yield, scalable, and cost-efficient production with industry-leading purity and low empty capsid rates. See “— Our Technology Platforms — The AAVANCE™ Manufacturing Platform.”

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, one clinical trial also used CRO for clinical management.

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. 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.

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- **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. 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 in Suzhou, Jiangsu province, China, occupying approximately 4,000 sq.m. of land. 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.

Our Suzhou manufacturing facility is equipped with sophisticated infrastructure and advanced process automation, supporting the full spectrum of rAAV gene therapy production. The facility features dedicated areas for upstream and downstream processing, including seed preparation, Bac/Sf9 cell amplification, large-scale bioreactor culture, harvest, purification, ultrafiltration/diafiltration, formulation, filling, packaging, and comprehensive quality control testing.

We utilize our proprietary 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. Currently, laboratory-scale rAAV production typically achieves yields in the range of 10^{12} – 10^{14} vg/L; in comparison, our process achieves upstream titers exceeding 10^{15} vg/L and downstream purification yields of 50%, significantly outperforming industry averages. Through innovative purification technologies, we consistently achieve empty capsid rates of less than 1%, minimizing immunogenicity and maximizing therapeutic efficacy. Our platform is compatible with multiple AAV serotypes and is designed for seamless scale-up from laboratory to commercial production volumes, currently with both 200L and 500L bioreactors. See “— Our Technology Platforms — The AAVANCE™ Manufacturing Platform.”

BUSINESS

Our 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. We have sufficient capacity to support clinical development and initial commercialization for these candidates.

The facility's flexible design and modular capacity allow us to efficiently accommodate increasing demand as our programs advance through late-stage clinical development and toward commercialization.

Leveraging our Suzhou facility and proprietary AAVANCE™ manufacturing platform, we have supplied high-quality rAAV gene therapy products for our clinical trials, and we are prepared to support commercial launch and global distribution upon regulatory approval.

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 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. This collaboration commenced in June 2021 and the contracted manufacturing concluded in September 2025. During this period, we entered into service agreements with the CDMO specifying the scope of manufacturing services, 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.

BUSINESS

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, combining an in-house sales force with professional partners to achieve optimal market penetration.

For products addressing rare diseases, we aim to establish a capable sales team and leverage relationships with third parties to reach the targeted patient population. We would also consider fast-to-market commercialization on the back of 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.

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, and (iv) professional service providers.

We have maintained stable business relationships with our major suppliers. To monitor the quality of supplies, we implement a standardized operating system, setting out the procedures and guidelines for quality control inspection. This includes rigorous supplier qualification and selection based on stringent quality standards, detailed material specifications, and standards that outline required characteristics.

During the Track Record Period, 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.

BUSINESS

Our purchases from our five largest suppliers in aggregate accounted for 28.1% and 33.1% of our total purchases for the years ended December 31, 2023 and 2024, respectively, and 34.9% for the nine months ended September 30, 2025. Our purchases from our largest supplier alone accounted for 7.3% and 10.1% of our total purchases for the year ended December 31, 2023 and 2024, respectively, and 13.3% for the nine months ended September 30, 2025.

<u>Rank</u>	<u>Supplier</u>	<u>Background</u>	<u>Main Products/ Services Provided</u>	<u>Purchase Amount (US\$ in thousand)</u>	<u>Percentage of Total Purchase (%)</u>	<u>Business Relationship Since</u>
For the Year Ended December 31, 2023						
1	Supplier A	A CRO company, based in China, and its affiliates	CRO services	1,377	7.3	2021
2	Supplier B	A property leasing and management company, based in the United States	Office space and laboratory facilities	1,176	6.2	2021
3	Supplier C	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	1,033	5.5	2021
4	Supplier D	An ophthalmic medical research company, based in China	Clinical equipment	876	4.7	2022
5	Supplier E	A CRO company, based in China	CRO services	822	4.4	2022
Total . . .				5,284	28.1	
For the Year Ended December 31, 2024						
1	Supplier B	A property leasing and management company, based in the United States	Office space and laboratory facilities	1,180	10.1	2021
2	Supplier C	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	986	8.5	2021
3	Supplier F	New drug research and development company, based in China	Preclinical study services	771	6.6	2024
4	Supplier G	A CRO company, based in China	CRO services	547	4.7	2024
5	Supplier H	A CRO company, based in the United States	CRO services	372	3.2	2021
Total . . .				3,856	33.1	

BUSINESS

<u>Rank</u>	<u>Supplier</u>	<u>Background</u>	<u>Main Products/ Services Provided</u>	<u>Purchase Amount (US\$ in thousand)</u>	<u>Percentage of Total Purchase (%)</u>	<u>Business Relationship Since</u>
For the Nine Months Ended September 30, 2025						
1	Supplier B	A property leasing and management company, based in the United States	Office space and laboratory facilities	1,306	13.3	2021
2	Supplier I	An international law firm, based in the United States	Legal services	608	6.2	2022
3	Supplier C	A property leasing and management company, based in China, and its affiliates	Office space and manufacturing facilities	580	5.9	2021
4	Supplier J	A CRO company, based in China	CRO services	520	5.3	2023
5	Supplier G	A CRO company, based in China	CRO services	409	4.2	2024
Total . .				3,423	34.9	

All of our suppliers in each year/period 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/period during the Track Record Period.

BUSINESS

EMPLOYEES

As of September 30, 2025, we had 49 employees, a majority of whom were based in China. The following table sets forth the number of our employees by function as of the same date.

Function	Number of Employees
CMC and manufacturing	22
Research and development	20
Management and administrative	7
Total	49

The following table sets forth the number of our employees by location as of the same date.

Location	Number of Employees
China	44
The United States	5
Total	49

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.

BUSINESS

INTELLECTUAL PROPERTY

We are committed to the development and protection of our intellectual properties. Our future success depends significantly on our ability to obtain and maintain robust patent coverage, as well as other forms of intellectual property and proprietary protections, for the key technologies, inventions, and know-how fundamental to our pipeline and technology platforms. Equally important is our capacity to defend and enforce these patents, preserve the confidentiality of our trade secrets, and ensure our freedom to operate without infringing upon, misappropriating, or otherwise violating the valid and enforceable intellectual property rights held by third parties.

As of the Latest Practicable Date, our patent portfolio consists of 21 patent applications, including seven Patent Cooperation Treaty (“PCT”) patent applications, four U.S. patent applications, three China patent applications (including one Hong Kong patent application), one Canada patent application, three European patent applications, two Japan patent applications, and one Australia patent application. Among these patent applications, there are 17 patent applications that have been published and four filed patent applications that are unpublished as of the Latest Practicable Date. Our patent applications primarily include compositions, methods and uses related to our drug candidates and technology platforms.

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

- FT-002: We had four patent applications in China, the United States, Europe, and Japan.
- FT-003: We had seven patent applications in China (including Hong Kong), the United States, Europe, Japan, Canada, and Australia.

BUSINESS

The following table summarizes the details of the material patent applications in connection with our Core Products, other drug candidates, and our technology platforms. For more details, please see “Appendix IV — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights — (c) Patents.”

Related Product or Technology Platform	Patent Application	Patent Applicant	Jurisdiction	Patent Status	Estimated Expiry ⁽¹⁾
FT-001	Compositions and methods for the treatment of ocular diseases	Frontera US	China, the United States	Pending	July 20, 2041
FT-002	Compositions and methods for the treatment of eye diseases	Frontera US	China, the United States, Europe, Japan	Pending	July 20, 2041
FT-003	Composition and method for treating eye diseases	Frontera US	China (including Hong Kong), the United States, Europe, Japan, Canada, and Australia	Pending	July 20, 2041
FT-017	Compositions and methods for the treatment of heart disease	Inspirar Limited	PCT	Published	January 27, 2045
FT-018	Nucleic acids and uses thereof for plakophilin 2 (PKP2) gene therapy	Inspirar Limited	PCT	Filed	September 1, 2045
FT-023	Compositions and methods for treating angiogenesis-related diseases or disorders	Inspirar Limited	PCT (provisional)	Filed	August 5, 2046
EXACTE™ platform	Recombinant adeno-associated virus with modified capsid polypeptides	Inspirar Limited	PCT (provisional)	Filed	September 29, 2046
AAVANCE™ platform	Methods for purification of adeno associated virus particles by anion exchange chromatography	Frontera US	PCT	Filed	March 21, 2045
AAVANCE™ platform	Methods for generating rhabdovirus-free cell line	Frontera US	PCT	Filed	May 7, 2045

Note:

- (1) The estimated expiry dates of patent applications are estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, and other government fees.

BUSINESS

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of gene therapy has emerged, and the patent situation is uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. We cannot provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our patents that may be issued in the future will be commercially useful in protecting our drug candidates and the methods of manufacturing the same. Moreover, our patents that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our drug candidates including the Core Products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our platforms and our drug candidates.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our Core Products, other drug candidates, and our technology platforms. We seek to protect Core Products, other drug candidates, and our technology platforms, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, consultants, CROs, and advisors. Our standard employment contract, which we have used to employ our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets conceived during the course of such employee's work or using our equipment or proprietary information.

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 date of this document, 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.

BUSINESS

COMPETITION

The biopharmaceutical and gene therapy industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe our robust pipeline of clinical and preclinical stage drug candidates, our EXACTE™ R&D and AAVANCE™ manufacturing technology platforms, and our well-established management team will provide us with competitive advantages, 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. Any drug candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

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.

We face competition from companies developing or testing drug candidates for the same or similar targets we are pursuing with our own pipeline. Please refer to “— Our Drug Candidates” and “Industry Overview” for further details of our major competitors. In addition, there may be additional competitors working on the targets of our critical programs of whom we are currently unaware.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer or more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain regulatory approval for their drugs earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition, and the availability of reimbursement from government and other third-party payers.

BUSINESS

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We believe our long-term success rests on our ability to make a positive impact on society. As we continue to bring innovative and effective gene therapy drugs to patients in China and worldwide, we strive to build a sustainable ecosystem comprised of our employees, collaborators and business partners, physicians, and patient groups.

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 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.

We are committed to strengthening our ESG oversight mechanisms by thoroughly integrating environmental, social, and governance factors into our business operations and ensuring compliance with relevant environmental protection laws and regulations. Recognizing the risks and opportunities associated with ESG, we are dedicated to identifying and addressing these factors through environmental impact assessments and management. We are exploring various measures to mitigate ESG-related risks while striving to balance cost-effectiveness with sustainable development. Our emissions reduction targets are based on industry standards and our specific circumstances, aiming to enhance our environmental performance in alignment with best practices. We plan to set up a timeline for achieving our ESG goals through a phased approach that ensures feasibility and traceability. Furthermore, we are committed to fostering a culture of compliance, with a goal to ensure that all employees are well-informed of and adhere to relevant ESG regulations and requirements through cross-departmental collaboration.

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.

BUSINESS

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. The waste is categorized into hazardous waste (such as chemical waste and liquid waste) and non-hazardous waste (such as waste from general office operations). The wastewater and solid waste generated during our in-house research, development and production process are pre-treated by our team before being handled by qualified third-party medical waste treatment companies. We have implemented a comprehensive hazardous waste management system. This includes 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. Scope 1 direct emissions include the greenhouse gas emissions from our manufacturing facility and other stationary combustion sources. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity and steam. Scope 3 includes greenhouse gas emissions generated by company employees' air travel and natural gas consumption in the leased buildings. 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 nine months ended September 30,
	2023	2024	2025
Greenhouse gas emissions			
Scope 1 greenhouse gas (tons of CO ₂ equivalent)	–	–	368.6
Scope 2 greenhouse gas (tons of CO ₂ equivalent)	4,487.0	4,524.0	2,614.0
Scope 3 greenhouse gas (tons of CO ₂ equivalent)	330.0	351.8	195.9
Total carbon emission (tons of CO₂ equivalent)	<u>4,817.0</u>	<u>4,876.0</u>	<u>3,178.0</u>
Total carbon emission intensity (ton per RMB1 million research and development expenses)	<u>25.3</u>	<u>32.9</u>	<u>38.5</u>

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To further reduce the company’s greenhouse gas emissions, we plan to implement low-carbon optimizations in laboratory facility maintenance, business travel, and office space selection areas.

Management of Environmental Protection Matters

We conduct environmental impact assessments to monitor emission levels. We use a range of metrics to evaluate the impact of environmental risks. Furthermore, we have set multiple objectives to reduce our environmental footprint and are actively pursuing significant measures to meet these targets. The following table sets forth the indicators related to our energy consumption and waste production during the Track Record Period.

	For the year ended December 31,		For the nine months ended September 30,
	2023	2024	2025
Energy consumption:			
Electricity (MWh)	3,190	3,449	1,764
Water (tons)	9,583	8,648	4,177
Waste:			
Hazardous waste (tons)	45	45	19

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, the company has 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 December 31, 2026, compared to the level on September 30, 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 established comprehensive internal policies to protect data integrity and prevent data manipulation, specifically outlined in our Data Integrity Policy and Information Security Management Policy regarding detection and response to data breaches and data loss, and the Compliance Disciplinary Policy. These policies establish clear guidelines for data handling and set forth consequences for policy violations. Together, they form a robust framework to safeguard the authenticity and reliability of our research and clinical data.

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Our contracts with R&D employees contain confidentiality clauses, adding an extra layer of security for the confidential information. Through these measures, we maintain a high standard of confidentiality and data protection throughout the clinical trial process.

Additionally, we generally require CROs to keep all documents, data, records, and information provided by us or generated during the contract strictly confidential. The CROs are also required to ensure that their employees, consultants, and other professionals who access this confidential information are bound by the same confidentiality obligations. Without our prior written consent, CROs are generally prohibited from disclosing, revealing, or disseminating any confidential information to third parties in any form. Additionally, to the extent possible, we require CROs to implement protective measures that are at least equivalent to those they use for their own confidential information, to prevent unauthorized use, disclosure, or leakage of the information provided by us or generated during the trial.

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.” Through the integration of rigorous quality standards and sustainable manufacturing practices, we strive to establish ourselves as a responsible participant in the gene therapy industry.

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.

BUSINESS

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 September 30, 2025, over two-thirds of our total employees were female. 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.

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. Our PRC Legal Advisor are of the view that the non-registration of our lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities may require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, our right to use such properties in accordance with the lease agreements would not be affected, but we may be subject to the risks of fines if lease registration is not completed as required by the relevant local housing administrative authorities. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. 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.

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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."

BUSINESS

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. See "Risk Factors" for a more detailed discussion on various risks we may subject to. In particular, we are exposed to credit, liquidity and currency risks that arise in the normal course of our business. See "Financial Information — Financial Risk Disclosure" for details on the above-mentioned market risks.

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, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operations and our management's handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group;
- 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

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- 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. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

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

Internal Control

Our Board 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. 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.

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. For more information, see "**— Intellectual Property**" and "**— Social, Health, Work Safety and Environmental Matters.**"
- We provide various training programs to keep our employees updated of relevant laws, regulations and policies. Our new employees are required to attend compliance training programs soon after on-boarding, and must pass tests which examine their understanding of the compliance issues addressed by the training programs. Our employees are also required to regularly attend further onsite and online training sessions to keep them informed of the recent updates in the relevant laws and regulations.

BUSINESS

- 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. Our compliance adviser is expected to ensure our use of funding complies with the sections entitled "Future Plans and Use of [REDACTED]" in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.
- We have engaged a PRC law firm to advise us on and keep us abreast with PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.
- We 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. In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery, including providing anti-corruption and anti-bribery compliance training for our Directors and senior management in order to enhance their knowledge and compliance of applicable laws and regulations. We require our employees, especially those involved in procurement, sales and marketing and other business functions which are more susceptible to bribery and corruptions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We also have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees.

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.