Certain information and statistics set out in this section have been extracted from various official government publications, market data providers and a report commissioned by us and prepared by an independent third party, Frost & Sullivan. The information from official government sources has not been independently verified by us, the Joint Sponsors, [**REDACTED**] *or any of their respective directors, officers, employees, advisers or agents or any other parties involved in the* [**REDACTED**].

THE ASSISTED REPRODUCTIVE DRUG MARKET

The assisted reproductive drugs are for the treatment of human infertility and mainly include ovulation-stimulating drugs, ovulation-inducing drugs, luteal support drugs and down-regulating drugs for women's reproductive health and pregnancy, as well as drugs for treatment of male symptoms, such as oligospermia. The market is poised for robust growth as demand increases.

Infertility and Treatments

Infertility is the inability to conceive after one year of regular, unprotected intercourse and can be attributed to female, male, or other factors. Female infertility primarily stems from fallopian tube diseases (such as pelvic infections or endometriosis) that can cause blockages, and ovulation disorders resulting from hormonal imbalances or uterine abnormalities. Male infertility is typically caused by abnormal semen transport due to structural blockages or sexual dysfunction, and abnormal sperm production linked to endocrine diseases or viral infections. Other contributing factors can include autoimmune issues, lifestyle choices (such as smoking and drinking), environmental exposures, and medical history involving certain drugs.

Prevalence of infertility

In 2025, there were 60.7 million infertile couples of reproductive ages in China, increased from 56.1 million in 2019 with a CAGR of 1.3%, which number is expected to increase to 68.8 million in 2030 with a CAGR of 2.5% from 2026 to 2030.

Forecast basis and assumptions

According to Frost & Sullivan, the analysis above is based on the following assumptions: (i) later marriage and childbirth: continued delays increase the share of advanced-age women, raising infertility prevalence; (ii) health and environmental factors: rising diabetes, PCOS, obesity, excessive stress and pollution are expected to worsen reproductive health, including male factors such as declining sperm quality; and (iii) awareness and access: higher awareness and wider availability of services are expected to increase adoption of IVF/ART and drive more couples to seek diagnosis and intervention.

In the field of infertility, there are challenges in estimating the number and proportion of patients suitable for each treatment option because (i) infertility does not have clearly defined and standardized sequential treatment pathways. Clinical guidelines are largely advised, rather than prescriptive therapies, and patients have broad flexibility to choose among lifestyle modifications, pharmacological treatments, ovulation induction, intrauterine insemination and in vitro fertilization. They may also switch between different options in a non-linear manner especially because rhFSH is frequently used in combination with LH and GnRH agonist/antagonist protocols within a COS cycle. Patients may receive several agents in the same cycle and may step up or down across "lines," so patient sets overlap and cannot be cleanly isolated by line. As a result, it is difficult to classify patients into specific treatment categories based on any unified sequence of care; (ii) whether a patient ultimately opts for a particular treatment is influenced by multiple non-medical factors, including financial affordability, sensitivity to treatment costs, family reproductive planning, personal and family fertility intentions, age-related fertility concerns, cultural considerations and the level of acceptance of assisted reproductive technologies. These factors can produce significant discrepancies between patients who are medically suitable for a given therapy and those who actually pursue that treatment pathway. For these reasons, the field lacks a stable, standardized and comparable model for estimating the applicable patient population and corresponding proportions.

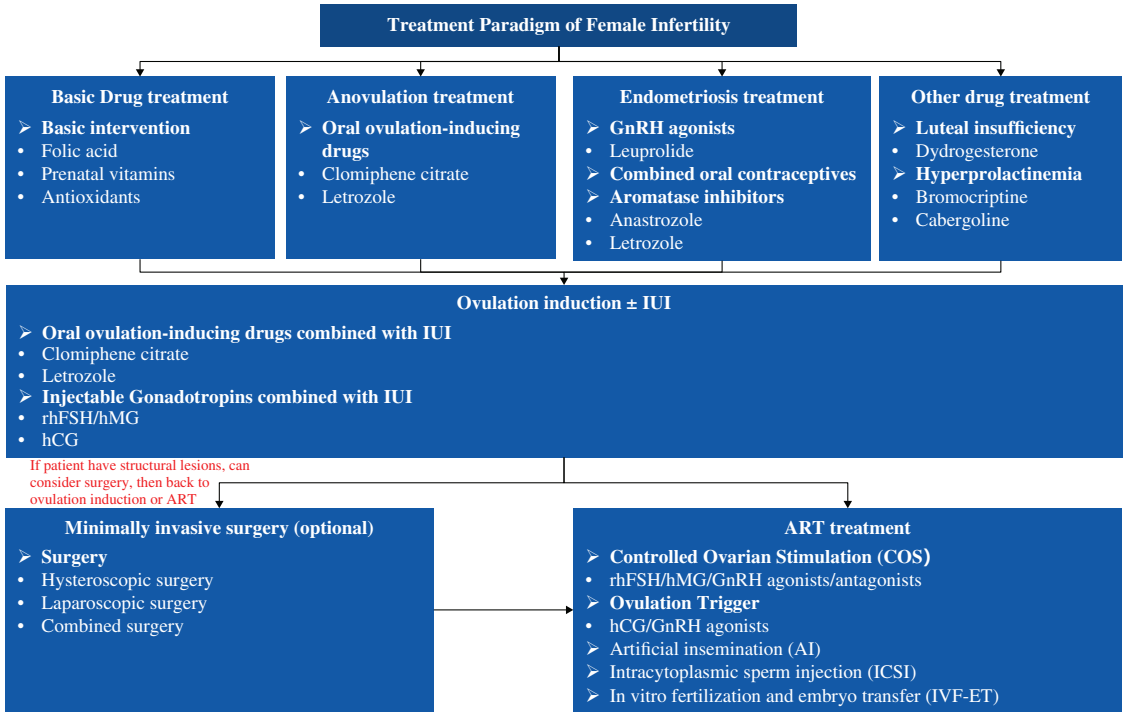
Treatment options

Infertility can be treated with medications, surgery and assisted reproductive technology (ART). Details are as follows: (i) *Medications*. Assisted reproductive drugs mainly include down-regulation drugs, ovulation-induction drugs and luteal support drugs for female symptoms, and drugs for male symptoms, such as oligospermia. Solving ovulation problems is the main focus of assisted reproductive drugs; (ii) *Surgery*. Abnormalities of the female reproductive system, such as endometriosis and Tubal Occlusion, can be treated with surgery. Laparoscopic surgery is a common type of surgery. In male patients, surgical treatments include varicocelectomy, vasectomy reversal, and epididymal vasostomy; (iii) *ART*. ART treatments include artificial insemination, in vitro fertilization and embryo transfer. In vitro fertilization and embryo transfer involve surgically removing eggs from a woman's ovaries, combining the eggs with sperm in the laboratory, and then transplanting the fertilized eggs into the uterus of the woman to be pregnant for the purpose of assisted reproduction. Assisted reproductive drugs are often used in ART procedures.

Treatment pathway for female infertility

Based on the latest domestic clinical guidelines, management of female infertility follows a stepwise pathway from oral ovulation induction with or without (±) intrauterine insemination (IUI), to injectable gonadotropins ± IUI, and then to ART, where appropriate. The following figure sets out this pathway, the proportion and number of patients clinically eligible for each line of therapy in China, and highlights the segments involving rhFSH.

Treatment Pathway for Female Infertility in China



Notes:

(1) The pathway reflects recent Chinese clinical guidance and expert consensus on infertility management. See Source below for citations.

(2) "Eligibility" refers to guideline-defined clinical suitability and does not represent actual utilisation.

(3) "rhFSH-addressable" denotes clinical settings where rhFSH may be used; any product use remains subject to regulatory approval and clinical judgement.

Source: Literature review, Clinical Practice Guideline for the Prevention and Treatment of Infertility in the Reproductive-Age Population (2024), Expert Consensus on Diagnostic and Therapeutic Pathways for PCOS, Chinese Expert Consensus on the Diagnosis and Management of Unexplained Infertility, Frost & Sullivan analysis

Assisted reproductive drugs

Assisted reproductive drugs for female symptoms target female reproductive hormone cycle and are mainly divided into (i) down-regulation for follicular phase, (ii) ovulation induction and stimulation for ovulation phase and (iii) luteal support drugs for luteal phase. Among them, ovulation stimulation drugs have the mechanism of controlling ovarian stimulation and promoting multi-follicular development, and constitute one of the most commonly used classes of assisted reproductive drugs in clinical practice.

Overview of FSH

FSH is one of the most important categories of assisted reproductive drugs. Natural FSH is a gonadotropin synthesized and secreted by the pituitarium. It promotes the development and maturation of follicles in women and promotes the maturation and spermatogenesis of testicular seminiferous tubules in men.

Similar to natural FSH, FSH drugs act on FSH receptors (FSHR) on target cells and bind to the G-protein-coupled transmembrane FSHR expressed on target cells, activating different signaling pathways and triggering different mechanisms of action based on specific physiological sex, development and environment. FSH drugs have different mechanisms in male and female groups. In women, the main role of FSH drugs is to regulate ovarian folliculogenesis and steroid hormone production. In men, FSH drugs play a role in regulating the maturation of testicular sertoli cells and sperm production.

FSH drugs can be categorized into urinary follicle-stimulating hormone (uFSH) drugs and rhFSH drugs based on their sources. Clinical data have shown rhFSH is more clinically effective than uFSH, because (i) rhFSH has high biological activity, which can improve embryo quality, gather more follicles and increase pregnancy rate, (ii) rhFSH can collect oocytes and obtain embryos at a lower total dose in a shorter treatment time and (iii) during the frozen-thawed embryo transfer treatment cycle, the clinical pregnancy rate of rhFSH cycle treatment is higher than that of uFSH cycle treatment. The following table summarizes the main differences between rhFSH and uFSH.

	rhFSH	uFSH
Source	• Produced by introducing the genes of human FSH alpha and beta subunits into Chinese hamster ovary cells through genetic engineering technology	• Extracted from gonadotropin hormones (hMG, including FSH) and LH in the urine of menopausal women
Preparation	• There are currently seven rhFSH preparations with slightly different compositions on the market • Human FSH alfa and beta are both obtained from cell culture supernatants through ultrafiltration, but are prepared through different chromatographic purification	• Use protein purification technology to remove LH and urine protein, and extract FSH. However, very small amounts of LH and urine protein will still be collected and lyophilized • According to the degree of purification, it is divided into FSH-P and FSH-HP preparations
Purity	• >99%	• FSH-P preparation>95%, FSH-HP>99%
Acceptance	• Higher, less pain in injection site, high drug purity	• Lower, injection is painful; sources are different, batch quality varies greatly; urine donor safety risk is high

Currently, from the perspective of dosage form, there are two main types of rhFSH on the market: rhFSH freeze-dried powder and water injection. The two types of dosage forms have similar therapeutic effectiveness and safety, but there are differences in clinical use, price, duration of efficacy, etc, allowing doctors to prescribe based on factors such as disease progression and financial ability of different patients. The freeze-dried powder drug needs to be dissolved into a solution and then injected for administration under the supervision of medical staff. For water injection, patients can inject themselves using recombinant human follicle stimulating hormone injection pen.

Main indications for rhFSH

The NMPA approved rhFSH for the treatment of patients with three types of infertility symptoms to stimulate either egg production or egg maturation: (i) adult female patients who do not ovulate and do not respond to clomiphene treatment, (ii) adult female patients who receive ovulation induction treatment through ART and (iii) adult female patients with severe LH and FSH deficiency. Internationally, the FDA and EMA have also approved rhFSH for use in male patients with hypogonadotropic hypogonadism. Clinical data have shown that rhFSH is 84% effective in treating female infertility symptoms, where rhFSH has a more consistent efficacy compared to human FSH in stimulating ovaries, and 63% effective in treating male infertility symptoms. The following table summarizes rhFSH's main indications and treatment options.

	Indications and Treatment Options	Approval Authority
Adult women	• Induction of ovulation and pregnancy in anovulatory infertile women with functional infertility (excluding primary ovarian insufficiency)	FDA & EMA & NMPA
	• rhFSH is used alone to stimulate the ovaries to produce multiple eggs at once	
	• Development of multiple follicles in ovulatory infertile women as part of ART cycles	FDA & EMA & NMPA
	• rhFSH is used alone to stimulate the ovaries to produce multiple eggs at once	
	• Severe lack of LH and FSH	EMA & NMPA
	• rhFSH is used with the drug LH to stimulate egg maturation in the ovaries	
Adult male	• Induction of spermatogenesis in infertile men with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure	EMA & FDA
	• Combined treatment with rhFSH and hCG can effectively stimulate sperm production	

Manufacturing process for rhFSH

rhFSH uses gene recombination technology to clone the human FSH gene into the genome of Chinese hamster ovary cells (CHO) and express it. After a series of cell expansion, separation and purification, quality inspection and other processes, the finished product of rhFSH is produced. Compared with uFSH, the production technical barriers of rhFSH are higher, and the production process of rhFSH is more stable, resulting in higher purity and uniform quality. Key production processes for rhFSH include (i) selecting appropriate and optimal target genes, vectors, cell lines and cell cultures to obtain rhFSH with high biological activity and purity; (ii) using an efficient and stable protein purification process to improve the rhFSH recovery rate and filter out high-purity and

highly active raw solutions; and (iii) conducting quality inspection tests, which mainly include biological activity, purity, exogenous DNA residues, bacterial endotoxin monitoring. The comprehensive quality inspection process can ensure uniform product quality, thereby reducing drug side effects and ensuring high safety of finished drug products.

Market Opportunities

Market size of assisted reproductive drugs in China

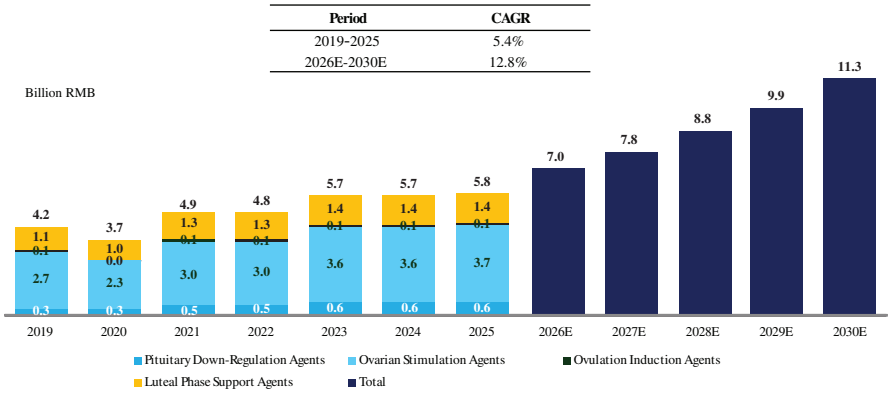
China's assisted reproductive drug market size increased from RMB4.2 billion in 2019 to RMB5.8 billion in 2025 with a CAGR of 5.4%. It is expected to continue to increase with a CAGR of 12.8% from 2026 to 2030, reaching RMB11.3 billion in 2030.

Forecast basis and assumptions

According to Frost & Sullivan, the analysis above is based on the following assumptions: (i) expanding patient pool: delayed marriage/childbirth and more reproductive health issues are expected to increase the number of infertile couples, lifting demand for drugs; (ii) ART adoption: progressive increases in IVF/ART adoption in hospitals and fertility centers are expected to expand the treated population; (iii) affordability and coverage: broader insurance coverage and improved ability to pay are expected to lower economic barriers and raise utilization; (iv) policy and awareness: two-child/three-child policies and rising awareness are expected to release latent demand; (v) product innovation: approvals of safer, more effective and more personalized regimens are expected to enhance market attractiveness.

This market comprises several key segments, including ovarian stimulation agents, luteal phase support agents, pituitary down-regulation agents and ovulation induction agents. Among these, the ovarian stimulation agents segment is the largest. In 2025, the market size of ovarian stimulation agents reached RMB3.7 billion, accounting for approximately 63.8% of the total assisted reproductive drug market in China. The following diagram illustrates the market size of the assisted reproductive drug market in China, broken down by its key segments, from 2019 to 2030.

Assisted Reproductive Drug Market in China, 2019-2030E



Source: Annual Reports of Listed Companies, Expert Interview, Frost & Sullivan Analysis

Market size of FSH drugs in China

FSH drug market is composed of two segments, rhFSH and uFSH. China's FSH drug market increased from RMB2.4 billion in 2019 to RMB3.3 billion in 2025 with a CAGR of 5.5%. It is expected to continue to increase to RMB7.2 billion in 2030 with a CAGR of 15.6% from 2026 to 2030.

China's rhFSH drug market reached RMB2.5 billion in 2025 with a CAGR of 6.8% from 2019 to 2025. It is expected to continue to increase to RMB6.1 billion in 2030 with a CAGR of 19.2% from 2026 to 2030, outpacing the growth rate of uFSH and taking more market share.

Forecast basis and assumptions

According to Frost & Sullivan, the analysis above is based on the following assumptions: (i) volume growth: increased IVF/ART adoption is expected to raise ovulation-induction and COS treatment volumes, expanding FSH use; (ii) reimbursement and import substitution: future inclusion of FSH drugs in medical insurance and approvals of more domestic products are expected to lower costs and promote utilization; (iii) long-acting and convenience: approvals of effective, safe and long-acting FSH options are expected to improve adherence and support growth.

The market size of oligospermia in China

Clinical trials evaluating rhFSH in infertility indications are ongoing. Notably, there is active domestic and international focus on multiple clinical studies investigating the role and mechanisms of rhFSH in the treatment of male infertility, including patients with oligospermia. Oligospermia, also known as low sperm count, is a condition in which a man has fewer sperm cells in his semen than normal and would lead to reduced fertility. In 2025, the number of patients with oligospermia in China was 95.9 million, growing from 92.6 million in 2019 with a CAGR of 0.6%. It is estimated that by 2030, the number of patients with oligospermia in China will reach 100.2 million, with a CAGR of 0.9% from 2026 to 2030.

The market size of idiopathic hypogonadotropic hypogonadism drugs in China

In 2025, the number of patients with idiopathic hypogonadotropic hypogonadism in China was 155.1 thousand, with a CAGR of 1.7% from 2019 to 2025. It is estimated that by 2030, the number of patients with idiopathic hypogonadotropic hypogonadism in China will reach 164.3 thousand, with a CAGR of 1.2% from 2026 to 2030. The size of idiopathic hypogonadotropic hypogonadism drugs market in China was RMB0.2 billion in 2025, with a CAGR of 12.9% from 2019 to 2025. It is expected to grow to RMB0.4 billion in 2030, with a CAGR of 8.2% from 2026 to 2030.

Growth drivers for China's assisted reproductive drug market

The assisted reproductive drug market is expected to be driven by (i) rising infertility rates in both men and women due to factors like delayed childbearing and lifestyle changes, which increases the fundamental demand for treatment; (ii) favorable government policies aimed at including ART services in health insurance, which, combined with growing public acceptance and rising incomes, improves affordability and boosts demand for clinically preferred modern drugs like rhFSH. The increased use of ART can in turn drive growth for FSH because controlled ovarian stimulation is a core component of almost all ART cycles and relies heavily on exogenous FSH to induce multifollicular development. Within gonadotropins, rhFSH is expected to gain share from urinary FSH. It has higher purity, superior batch-to-batch consistency, and more predictable pharmacokinetics, enabling more precise dosing and improved cycle management in ART settings, which bring clinical and operational advantages and make rhFSH the preferred option in modern IVF protocols. In addition, import substitution, process optimization and multi-specification offerings, longer-acting regimens and potential indication expansion (e.g. male hypogonadotropic hypogonadism) may further support uptake. Therefore, policy-driven expansion of ART access, combined with rising patient affordability and growing preference for safer, more reliable therapies, is expected to disproportionately accelerate demand for rhFSH; For example, China's 2024 Several Measures to Accelerate the Improvement of the Fertility Support Policy System explicitly enhances ART access by encouraging eligible localities to include appropriate ART procedures and childbirth-related services in public medical insurance. The policy is complemented by broader birth-support measures such as improved maternity care, childcare services, and workplace protections, which together reduce financial burden and practical barriers for individuals seeking ART and (iii) the continued expansion of licensed assisted reproductive facilities across China, which increases service capacity and drives higher demand for the medications used in ART treatments.

Competitive Landscape of rhFSH Drugs in China

There were nine rhFSH injection marketed in China as of the Latest Practicable Date, including the reference drug (GONAL-F®) by Merck, further details of which are set forth below.

Marketed Recombinant Human Follicle Stimulating Hormone (rhFSH) in China

Drug name	Generic name	Company	Drug type	First approval date	Indications
泽盼喜®	Recombinant Human Follitropin for Injection	Jingze	Biosimilar	2025/04/30	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency
丽优宝®	Recombinant Human Follitropin Alfa Solution for Injection	Livzon	Biosimilar	2026/05/27	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency
康诺冠®	Recombinant Human Follitropin Alfa Solution for Injection	Alphamab Oncology	Biosimilar	2025/11/25	• Used in combination with gonadotropin-releasing hormone antagonists for controlled ovarian stimulation to promote the development of multiple follicles
Rekovelle®	Human Follitropin delta injection	Ferring	New drug	2024/04/30	• Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART)
Anxinbao®	Recombinant Human Follitropin for Injection	Qilu	Biosimilar	2021/12/14	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency
Follitrope®	Recombinant Human Follitropin Prefilled Syringe	LG Chem	Biosimilar	2021/04/07	• For patients undergoing superovulation or Assisted Reproductive Technology (ART);
Jinsaiheng®	Recombinant Human Follitropin for Injection	GeneScience	Biosimilar	2015/05/27	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART);
PUREGON®	Recombinant Follitropin Beta Injection	Organon	New drug	2005/10/28	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART);
GONAL-f®	Recombinant Human Follitropin Injection	Merck	New drug (Reference drug)	2000/04/26	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency.

Notes:

(1) As of the Latest Practicable Date

(2) NRDL: As of the Latest Practicable Date, none of the marketed rhFSH products in China were included in the National Reimbursement Drug List (NRDL).

(3) Exclusivity (China): No current regulatory exclusivity has been disclosed for marketed rhFSH products in China. Patents relating to GONAL-f® did not enter China (see "Business — Our Drug Candidates — Our Assisted Reproductive Drug Candidates — Our Core Product: JZB30 (a biosimilar to Gonal-F® lyophilized form) — Background of reference drugs").

Source: NMPA, Frost & Sullivan analysis

Our Core Product JZB30 (rhFSH, lyophilised) is approved in China for: (i) anovulatory women unresponsive to clomiphene; (ii) COS as part of ART (e.g. IVF/ICSI); and (iii) severe LH and FSH deficiency in adult women. For these indications, according to the Frost & Sullivan analysis, NMPA-approved comparators include: (i) anovulatory women unresponsive to clomiphene: GONAL-f®, PUREGON®, Jinsaiheng®, Anxinbao®, Follitrope®, 麗優寶®, and urofollitropin products (e.g. Fostimon®, 麗申寶®); (ii) COS: GONAL-f®, 康諾冠®, PUREGON®, Rekovelle®, Jinsaiheng®, Anxinbao®, Follitrope®, MENOPUR® (menotropin), Fostimon® 麗優寶®, and 麗申寶® (urofollitropin); (iii) severe LH and FSH deficiency (adult women): GONAL-f® 麗優寶®, and Pergoveris®, Anxinbao®.

As of the Latest Practicable Date, there were two short-acting clinical-stage rhFSH candidates in China (two of which have entered the registration application stage) and further details of which are set forth below.

		Drug name	Drug category	Original drug	Generic name	Company	Indication	Stage	First posted date
rhFSH	1	JZB33	Biosimilars	Follitropin alfa	rhFSH injection	Jingze	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency	NDA	2025/06/27
	2	QL-1012D	Biosimilars	Follitropin alfa	rhFSH injection	Qilu	• Women who do not ovulate and do not respond to clomiphene treatment; • For patients undergoing superovulation or Assisted Reproductive Technology (ART); • For patients with severe LH and FSH deficiency	NDA	2026/06/25

Source: CDE, Frost & Sullivan analysis

According to Frost & Sullivan, given JZB30's targeted commercialization in January 2027 several domestic short-acting rhFSH biosimilars that are currently at or near the NDA/registration stage could obtain approval and enter the market by that time, subject to regulatory approvals. Therefore, the competitive landscape at launch may include both JZB30 marketed brands and newly approved domestic biosimilars.

Additionally, according to Frost & Sullivan, as of the Latest Practicable Date, no drug had been approved in China for the treatment of hypogonadotropic hypogonadism, and two drug candidates in China were under clinical stage. Outside China, the hypogonadotropic hypogonadism indication of GONAL-f® is approved in the United States and the European Union.

Competitive Landscape of Idiopathic Hypogonadotropic Hypogonadism in China

Drug name	Company	Target	Clinical stage	Indication	First posted date
JZB30	Jingze	FSHR	Phase 3	Idiopathic hypogonadotropic hypogonadism	2023-06-19
SAL 016	GeneScience	FSHR	Phase 3		2024-08-19

Note: As of the Latest Practicable Date.

Source: CDE, Frost & Sullivan analysis

Several market trends are poised to support the growth of domestically produced rhFSH drugs including (i) a significant opportunity for import substitution as domestic R&D and production capabilities mature, enabling local products to capture share in the currently import-dominated market; (ii) the ongoing displacement of older, less pure uFSH by clinically superior rhFSH as domestic manufacturing becomes more cost-effective; (iii) product innovation, such as the development of long-acting formulations to improve patient compliance and multi-specification products to enhance clinical convenience; and (iv) the potential for new markets to open up through favorable policy changes, such as allowing egg freezing for single women.

Entry barriers for China's Assisted Reproduction Drug Market

Notwithstanding the growth drivers described above, the assisted reproduction drug market in China also presents the following entry barriers: (i) *Technical barriers.* Core molecules (e.g. recombinant FSH) require advanced gene expression and purification technologies and stringent quality consistency; reliance on imported inputs persists; (ii) *Stringent regulatory approval.* Local clinical data, robust GMP systems and extensive documentation are required. The review process is resource-intensive; (iii) *High clinical trial costs.* Trials often depend on specialized IVF centers, standardized labs and long follow-up, elevating cost and failure risk; (iv) *Cold-chain logistics.* Biologics used in ART require strict temperature control throughout storage and transport, adding capital and operational burdens.

Market-level Challenges and Threats for China's Assisted Reproduction Drug Market

In addition to these entry barriers, the assisted reproduction drug market faces the following market-level challenges and threats: (i) *Limited insurance coverage and price sensitivity.* Many ART drugs are not reimbursed or only partially reimbursed; even when listed, prices are negotiated down materially; (ii) *Low awareness and misconceptions.* Stigma and misinformation in some regions depress conversion from the latent patient pool to treatment-seeking; (iii) *Legal and ethical uncertainty.* Access for single women (e.g. egg freezing) and other boundaries of ART remain under policy debate, increasing operational uncertainty; (iv) *Imbalance in medical resources.* IVF capacity is concentrated in top-tier cities; access constraints in lower-tier regions suppress latent demand; and (v) *Social and economic headwinds.* Rising age at first marriage, growing non-marriage/singlehood among people of prime child-bearing age, individualist lifestyles and high child-rearing costs reduce willingness to reproduce, which may limit growth in demand for ART and related drugs.

THE OPHTHALMIC DRUG MARKET

Ophthalmic drugs are for the treatment of various eye conditions, mainly including anterior segment diseases and posterior segment diseases. Under the anterior segment diseases, the main ophthalmology drugs category includes anti-inflammation/infection drug, anti-glaucoma drug, dry eye disease drug and anti-allergic drug. Under the posterior segment diseases, the main ophthalmology drug category includes anti-neovascularization drug, glucocorticoid drug and antibiotics.

The Ophthalmic Diseases and Treatments

Ophthalmic diseases refer to the conditions that affect any of the eye components such as cornea, optic nerve, lens, retina, choroid and ocular surface. According to WHO report on vision, ophthalmic diseases are categorized by non-vision threatening including conjunctivitis, pterygium, pinguecula, blepharitis and dry eye disease and vision threatening, including retinal diseases, cataract, glaucoma, and uveitis. In the absence of timely treatment, some non-vision-threatening eye diseases may lead to a variety of severe complications and carry the risk of vision loss. Posterior segment diseases are generally more severe and carry a higher risk of blindness. In China, eye diseases are generally treated by ophthalmologists of finely divided specialties and sub-specialties, such as retinal specialists and corneal specialists. There is a shortage of qualified practitioners, particularly those with sub-specialty skills and standard of care for some indications, such as non-infectious uveitis.

As a major category of ophthalmic diseases, retinal diseases affect the back of the eye, which include conditions such as FNDs. Additionally, VMA caused by the adhesion between the eye vitreous gel and the retina internal limiting membrane may also result in pathologies such as sVMA or vitreomacular traction syndrome.

Overview of FNDs

FND refers to an eye disease that affects vision due to pathological changes such as hemorrhage, exudation, and hyperplasia caused by neovascular growth. Environment and genetics are the main risk factors, and other factors include diabetes, hypertension and age. As the disease progresses, it causes retinal detachment, macular edema and significant vision impairment or even blindness if left untreated.

Major FNDs

Major FNDs and their respective symptoms and major risk factors include: (i) *wAMD*. Wet age-related macular degeneration is a severe form of AMD characterized by the abnormal growth and leakage of blood vessels under the macula, leading to rapid central vision loss, retinal damage, and potential blindness. Although it accounts for only about 10% of AMD cases, wAMD is responsible for 80– 90% of vision loss associated with the disease, with risk factors including aging, genetics, smoking, and prior AMD in one eye; (ii) *DR*. Diabetic retinopathy is a diabetes complication that damages retinal blood vessels and can cause blindness if untreated. Proliferative DR and DME are neovascular complications, with rising prevalence due to increasing diabetes and risk factors like hypertension; (iii) *RVO*. Retinal vein occlusion is a blockage of retinal veins that can cause vision loss. It is classified into central and branch types, with risk factors including aging, hypertension, arteriosclerosis, and hyperlipidemia; (iv) *mCNV*. Myopic choroidal neovascularization is a myopia-related complication where abnormal blood vessels form in the choroid, leading to vision loss. It often affects both eyes over time, with risk factors including myopia, aging, female gender, and macular changes.

Prevalence of FNDs

The number of patients with a FND, such as wAMD, DR, RVO and mCNV, has been growing and is expected to continue to grow in China, due to factors such as aging population and changing lifestyles. In 2025, the number of addressable patients with FNDs in China reached 55.1 million, growing from 47.7 million in 2019 with a CAGR of 2.4%. It is estimated that there will be 61.6 million FND patients in China by 2030, with a CAGR of 2.3% from 2026 to 2030.

In the field of retinal diseases, estimating the number and proportion of patients suitable for each treatment option faces inherent challenges. Retinal diseases do not follow a strict or widely accepted sequential treatment framework, and there is no fixed order among the available therapeutic approaches. While anti-VEGF is first-line in Chinese guidelines, real-world practice differs across centers (e.g., monthly, PRN, treat-and-extend), and patients may switch molecules. For common conditions such as diabetic retinopathy, age-related macular degeneration and diabetic macular edema, treatments including anti-VEGF injections, laser therapy, intravitreal corticosteroids and observation may all serve as initial or subsequent options. Physicians make treatment decisions based on factors such as disease stage, visual function, prior treatment responses and the patient's ability to adhere to long-term follow-up. Patients' actual choices are further influenced by financial affordability, acceptance of repeated injections and other psychological considerations. Furthermore, there is no authoritative national registry that reports per-line shares, and guidelines do not publish per-line percentages. As a result, it is difficult to categorize and quantify the patient population according to a single, standardized clinical pathway.

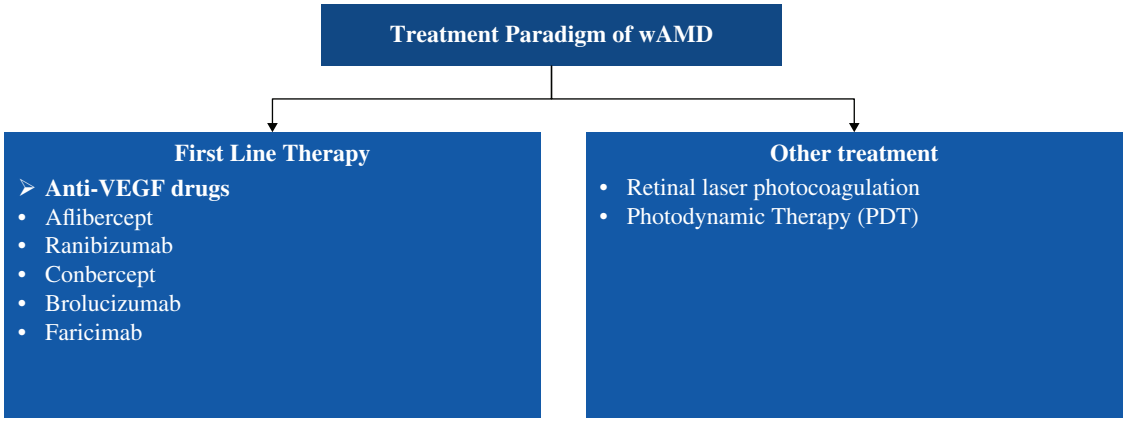
Anti-VEGF therapy as recommended treatments

Furthermore, various FNDs guidelines in China have recommended anti vascular endothelial growth factor drugs as the main treatment drugs for FNDs. As of the Latest Practicable Date, anti-VEGF drugs have been approved in China for the treatment of various FNDs, including (i) *wAMD*. Intravitreal anti-VEGF drugs are recommended by "Clinical Pathway of Age-related Macular Degeneration in China" for first-line and combination regimens for multiple subtypes of wAMD; (ii) *DR*. Anti-VEGF agents are recommended for first-line treatment of clinically significant DME, the highest grade lesion type in the clinical diagnosis and treatment of the macula,

and are recommended for multiple combination therapies. Other treatment options include glucocorticoids, laser therapy and vitrectomy; (iii) *RVO*. Anti-VEGF agents are recommended by "Expert Consensus on Clinical Diagnosis and Treatment Path of Retinal Vein Occlusion in China" for first-line treatment of RVO. Other treatment options include glucocorticoids, laser therapy, and a variety of surgical options; and (iv) *mCNV*. Intravitreal anti-VEGF drugs are the preferred treatment options for mCNV as recommended by "Choroidal Neovascularization Secondary to Pathologic Myopia."

Under the latest Chinese guideline for age-related macular degeneration, intravitreal anti-VEGF therapy is first-line for wAMD, while photodynamic therapy (PDT) or retinal laser may be considered in selected cases. The figure below outlines this pathway, showing eligibility by treatment category and the anti-VEGF segment.

Treatment Pathway for wAMD in China



Notes:

(1) "Eligibility" refers to guideline-defined clinical suitability and does not represent actual utilization.

(2) The anti-VEGF segment is where aflibercept-class products are used; any specific product use depends on product labeling and regulatory approval for the relevant indication.

(3) Presenting line by line numerical percentages in the pathway diagrams for wAMD/anti-VEGF would not be sufficiently reliable because while anti-VEGF is first-line in Chinese guidelines, real-world practice differs across centers (e.g., monthly, PRN, treat-and-extend), and patients may switch molecules. Injection frequency and exposure by "line" are therefore highly variable. There is no authoritative national registry that reports per-line shares, and guidelines do not publish per-line percentages. Any granular split would rely on strong assumptions and would not be generalisable.

Source: Evidence-based guidelines for diagnosis and treatment of age-related macular degeneration in China (2023), Frost & Sullivan analysis

Other ophthalmic treatments, such as therapies for dry eye, glaucoma, refractive errors, or cataracts, are clinically and competitively unrelated to anti-VEGF therapies because they address different disease mechanisms and patient populations. FNDs are driven specifically by pathological VEGF-mediated angiogenesis, for which anti-VEGF agents are the standard and mechanistically appropriate therapy. As a result, products outside the anti-VEGF class neither substitute for nor meaningfully compete with treatments for FNDs.

Overview of VMA

VMA is a condition where the eye's vitreous gel abnormally adheres to the retina's central macula, exerting traction that can lead to significant vision loss and other pathologies. The primary treatment is pars plana vitrectomy (PPV), an invasive and high-risk surgery. However, a non-surgical option, ocriplasmin (JETREA®), offers a key alternative.

Ocriplasmin is the only approved drug for VMA, acting as a "molecular scalpel" that is injected into the eye to enzymatically dissolve the proteins causing the adhesion, thereby releasing the traction. It has demonstrated high efficacy in clinical trials. Compared to PPV, ocriplasmin provides significant safety advantages: it is a minimally invasive injection that can be performed in minutes by most county-level doctors, has a low risk of complications, and requires a simple recovery of a few days. In contrast, PPV is a difficult surgery with risks of serious complications like retinal tears and requires a burdensome post-operative recovery involving weeks of face-down positioning.

Crucially, ocriplasmin allows for earlier intervention before significant vision loss occurs, a key benefit as the high-risk PPV surgery is often delayed until a patient's vision is severely impaired.

Prevalence of sVMA

The number of sVMA patients in China grew from 37.1 million in 2019 to 42.9 million in 2025, with a CAGR of 2.5%. It is estimated that by 2030, the number of sVMA patients in China will reach 48.6 million, growing with a CAGR of 2.5% from 2026 to 2030. The increasing prevalence of sVMA signals a growing market demand for effective therapeutic interventions to address this condition. As a non-surgical solution, ocriplasmin presents a promising opportunity to meet this rising unmet medical need.

Market Opportunities

Market size of ophthalmic drug in China

China's ophthalmic drug market size increased from RMB19.4 billion in 2019 to RMB31.5 billion in 2025 with a CAGR of 8.4%. It is expected to continue to increase to RMB51.9 billion in 2030 with a CAGR of 11.2% from 2026 to 2030.

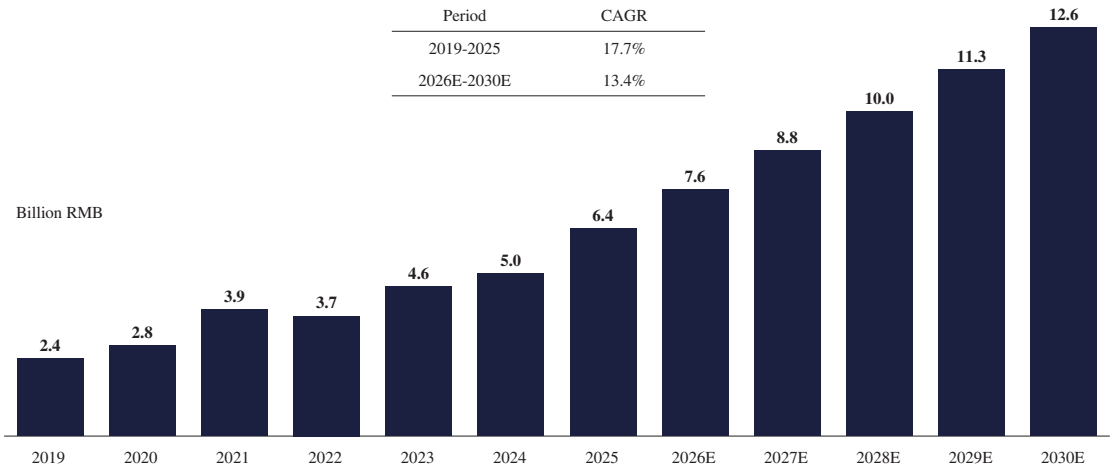
Forecast basis and assumptions

According to Frost & Sullivan, the analysis above is based on the following assumptions: (i) ageing: the global 65+ population is expected to exceed 900 million by 2030, with ageing in China increasing age-related eye diseases; (ii) disease burden and behaviors: rising diabetes prevalence and prolonged digital-screen use are expected to increase DR and dry-eye incidence; (iii) coverage and access: improvements in insurance coverage and wider availability of diagnostics and therapies are expected to increase diagnosis and treatment.

Market size of anti-VEGF drugs in China

The market size for anti-VEGF antibody drugs used to treat FNDs in China increased from RMB2.4 billion in 2019 to RMB6.4 billion in 2025 with a CAGR of 17.7%. It is expected to continue to increase to RMB12.6 billion in 2030 with a CAGR of 13.4% from 2026 to 2030.

Market size and forecast of anti-VEGF drugs for fundus diseases in China, 2019-2030E



Source: Annual Reports of Listed Companies, Expert Interview, Frost & Sullivan Analysis

Forecast basis and assumptions

According to Frost & Sullivan, the analysis above is based on the following assumptions: (i) demographics: China's 65+ population is expected to reach 263.7 million by 2030, increasing AMD, DR and related conditions and lifting demand for VEGF inhibitors; (ii) underlying morbidity and behaviors: rising diabetes prevalence and prolonged screen use are expected to increase ophthalmic disease burden, supporting greater use of VEGF inhibitors; (iii) coverage, guidelines and reach: expanding medical-insurance coverage, inclusion of VEGF drugs in more guidelines and deeper penetration into secondary and tertiary cities are expected to increase diagnosis and treatment.

As of the Latest Practicable Date, there were five anti-VEGF molecules approved for FNDs in China, including aflibercept, ranibizumab, conbercept, faricimab and brolucizumab. In 2025, five were sold in China: aflibercept, ranibizumab, conbercept, faricimab and brolucizumab accounted for 20.0%, 21.5%, 38.1%, 19.6% and 0.8% of total anti-VEGF biologics market in China for FNDs, respectively, in terms of sales revenue. Aflibercept has the following advantages compared to the other four biologics: (i) compared to ranibizumab and brolucizumab, aflibercept has a broader range of targets, effectively modulating multiple angiogenic signaling pathways and suppressing inflammatory responses; (ii) compared to conbercept, it is supported by a large body of real-world data globally, including long-term follow-up studies, providing clinicians with comprehensive references on efficacy and safety; and (iii) compared to faricimab, while faricimab shows potential in extending injection intervals, aflibercept holds clear advantages in global market acceptance, breadth of approved indications and physician trust.

Market trends and growth drivers

China's ophthalmic market is expected to be driven by (i) a growing number of diagnosed patients, resulting from rising public awareness, an aging population, and lifestyle changes, which is supported by favorable government policies like the "14th Five-Year National Eye Health Plan"; (ii) breakthroughs in diagnostic and treatment technologies that improve patient outcomes and enable the expansion of drug indications to new diseases; and (iii) the increasing penetration of high-quality domestic drugs as local pharmaceutical companies mature, which fosters a more competitive landscape and attracts investment to expand the market.

Entry Barriers for China's Ophthalmic Drug Market

Notwithstanding the growth drivers described above, the ophthalmic drug market in China has the following entry barriers: (i) *Technical barriers*. Retinal therapeutics demand precision, durability and safety, often with innovative delivery/sustained-release technologies and imperfect preclinical predictability; (ii) *Market competition*. Multinational incumbents hold strong positions with extensive data and physician trust; specialty channel access and promotion are costly; (iii) *Patent barriers*. Layered patents on compounds, formulations and devices extend exclusivity and may trigger litigation or high licensing costs; (iv) *High R&D costs*. Ocular pharmacology and delivery challenges (e.g. blood-retina barrier, stability) increase complexity and spend.

Market-level Challenges and Threats for China's Ophthalmic Drug Market

In addition to these entry barriers, the ophthalmic drug market faces the following market-level challenges and threats: (i) *Manufacturing and supply-chain risks*. Ophthalmic production requires asepsis, precise formulation and cold-chain; shortages or inspection delays can cause supply disruption; (ii) *Emerging alternative technologies*. Gene/cell therapies, sustained-release implants and non-invasive delivery may cannibalize sales of established drugs; (iii) *Shifting expectations*. Patients and physicians prefer less invasive, longer-acting options and value real-world and economic evidence, influencing adoption; (iv) *Hospital access pressure*. Volume-based procurement and formulary controls heighten price pressure and raise uncertainty in hospital listing and uptake.

Competitive Landscape

As of the Latest Practicable Date, there are five original VEGF monoclonal antibody drugs for the treatment of fundus diseases on the market in China, namely LUCENTIS®(Novartis), EYLEA® (Bayer), Langmu®(Kanghong), VABYSMO®(Roche) and BEOVU® (Novartis), and three biosimilars marketed in China for ranibizumab and aflibercept, respectively.

As of the Latest Practicable Date, there are 12 anti-VEGF candidates in Phase III or later clinical development for the treatment of FNDs in China. The diagram below sets forth each drug candidate in greater detail.

	Drug name	Drug category	Original drug	Company	Indications	Stage	First posted date[1]	Target
1	BAT5906	New drug	/	Bio-Thera Solutions	wAMD	BLA	2025-12-19	VEGF
					DME	Phase III	2024-09-14	
2	601A	Improved new drug	Bevacizumab	3SBio	RVO-related macular edema	BLA	2025-10-15	VEGF
3	flimrufusp alfa	New drug	/	Remegen	DME	BLA	2025-09-30	FGF2 | VEGF
					wAMD	Phase III	2023-01-12	
4	9MW0813	Biosimilar	Aflibercept	Mabwell	DME, wAMD	BLA	2025-09-19	VEGF
5	HLX04-O	Improved new drug	Bevacizumab	Henlius	wAMD	BLA	2025-08-13	VEGFA
6	JL14002	Biosimilar	Ranibizumab	Jecho Biopharma	wAMD	BLA	2025-06-18	VEGFA
7	TAB014	Improved new drug	Bevacizumab	BioDlink	wAMD	BLA	2025-06-12	VEGFA
8	HJY28	Biosimilar	Ranibizumab	East China	wAMD	BLA	2025-05-30	VEGFA
9	JZB05	Biosimilar	Aflibercept	Jingze	DME	Phase III	2023-09-04	VEGF
10	LX102	New drug	/	Innostellar Biotherapeutics	wAMD	Phase III	2026-01-13	VEGF
11	Efdamrofusp alfa	New Drug	/	Innovent Biologics	wAMD	Phase III	2023-07-28	VEGF | C3b | C4b
12	RG6321	Improved New Drug	Ranibizumab	Roche	wAMD	Phase III	2022-10-13	VEGFA

Note:

* As of the Latest Practicable Date, first posted date means the first public disclosure date of clinical trial. Drugs that have reached regulatory approval are not included.

Source: CDE, Frost & Sullivan analysis

Competitive landscape of aflibercept drugs in China

As of the Latest Practicable Date, there are three approved aflibercept drugs for the treatment of FNDs in China, namely EYLEA® (Bayer), 卓初明® from Qilu Pharmaceuticals and 博優景® from Luye Pharma. The diagram below sets forth each drug in greater detail.

Competitive Landscape of Approved Aflibercept in China

NMPA Approved Aflibercept

	Brand name	Generic name	Company	Target	Drug type	Reference drug	Indication	First approval date	Annual cost (RMB)	2025 Market share
1	Eylea®	Aflibercept	Bayer	VEGF	New drug	–	DME, wAMD	2018-02-02	wAMD: 23,480 DME: 23,480	16.4%
2	卓初明®	Aflibercept	Qilu Pharmaceuticals	VEGF	Biosimilar	Eylea®	DME, wAMD	2023-12-13	wAMD: 19,760 DME: 19,760	2.8%
3	博优景®	Aflibercept	Luye Pharma	VEGF	Biosimilar	Eylea®	DME, wAMD	2025-11-25	wAMD: 18,785 DME: 18,785	0.7%

Notes:

(1) As of the Latest Practicable Date.

(2) NRDL: Aflibercept injection is included in the 2019 edition of the NRDL at the generic-name level (see "Business — Our Drug Candidates — Our Ophthalmic Drug Candidates — Our Core Product: JZB05 aflibercept solution (a biosimilar to Eylea®) — Background of reference drugs").

(3) Exclusivity (China): The molecular patent for Eylea® in China expired in 2020.

(4) Annual cost is calculated based on the labeled regimen; 2025 market share refers to sales revenue share of anti-VEGF biologics for fundus diseases in China in 2025.

Source: NMPA, Frost & Sullivan Analysis

Our Core Product JZB05 (an aflibercept biosimilar candidate) targets fundus neovascular indications in China, including DME, for which a Phase 3 study has been completed, and wAMD, which is an intended indication. According to the Frost & Sullivan analysis, NMPA-approved comparators include: (i) DME: EYLEA®, 卓初明® and 博優景® (aflibercept), LUMITIN® (conbercept), LUCENTIS® and 安卓明® (ranibizumab), VABYSMO® (faricimab), Beovu® (brolucizumab), and OZURDEX® (dexamethasone intravitreal implant); and (ii) wAMD: EYLEA®, 卓初明® and 博優景® (aflibercept), LUMITIN® (conbercept), LUCENTIS® and 安卓明® (ranibizumab), and VABYSMO® (faricimab).

As of the Latest Practicable Date, there were two biosimilars of aflibercept other than our JZB05 that are being investigated to treat DME. The diagram below sets forth each such drug candidates in greater detail.

Competitive Landscape of Aflibercept Biosimilar in Clinical Stage in China

Aflibercept in clinical stage in China

	Drug name	Drug type	Original drug	Target	Clinical Stage	Company	Indication	First posted date
1	9MW0813	Biosimilar	Aflibercept	VEGF	BLA	Mabwell Bioscience	DME, wAMD	2025-09-19
2	JZB05	Biosimilar	Aflibercept	VEGF	Phase III	Jingze Biopharma	DME	2023-09-04

Source: CDE, Frost & Sullivan analysis

Competitive landscape of VMA

As of the Latest Practicable Date, there is no ocriplasmin marketed in China, and our JZB32 was the only ocriplasmin drug candidate being evaluated for VMA in clinical trials in China. The diagram below sets forth drug candidates globally for treating sVMA as of the Latest Practicable Date.

Global marketed VMA drug

	Brand name	Generic name	Company	Indication	Regulatory authority	First approval date
1	JETREA®	Ocriplasmin	ThromboGenics	VMA	FDA	2012-10-17

The following diagram lists the competitive landscape of candidates for the treatment of sVMA in China as of the Latest Practicable Date.

	Drug name	Generic name	Company	Indication	Stage	First posted date
1	JZB32	Ocriplasmin	Jingze	VMA, PCV	I	2020-09-07

Source: CDE, FDA, Clinical Trials and Frost & Sullivan Analysis

Note: Reflects global R&D pipeline, excluding assets with no meaningful progress in the past 3-5 years.

Source of Information

In connection with the [**REDACTED**], we engaged Frost & Sullivan, an independent global market research and consulting firm established in 1961, to prepare an industry report on markets relevant to our business. We paid an aggregate fee and expenses of RMB0.6 million for the preparation of the report. The payment was not contingent upon the success of our [**REDACTED**] or upon the contents or conclusions of the report. Except for the Frost & Sullivan report, we did not commission any other industry report for the purposes of this document.

Frost & Sullivan conducted both primary and secondary research on the PRC and global markets for biosimilars, assisted reproductive drugs (including FSH), ophthalmic drugs (including anti-VEGF therapies) and related areas. Its research drew upon its proprietary databases, publicly available sources (including government publications and statistics, industry associations, academic literature, company annual reports and public filings), and interviews with market participants on the demand and supply sides. Where appropriate and necessary, Frost & Sullivan contacted companies in industries to gather and synthesize information in relation to the market, prices and other relevant information. Forecasts in this section are, unless otherwise stated, those of Frost & Sullivan. In preparing its forecasts, Frost & Sullivan made, among other things, certain key assumptions that (i) the social, economic and political environments in the PRC will remain broadly stable over the forecast period and support steady development of the healthcare industry; (ii) global healthcare demand and supply will grow as expected; and (iii) governments will continue to support healthcare reform. These assumptions are supported by several long-term structural trends. First, Mainland China has maintained a broadly stable social, economic and policy environment, with continued prioritization of healthcare as a strategic sector under national planning, which underpins steady industry development. Second, global healthcare demand is expected to rise due to population aging, chronic disease burden, and ongoing innovation in diagnostics and therapeutics, while supply expansion is driven by sustained investment, technological advances, and improved manufacturing capacity. Third, governments worldwide including China continue to promote healthcare reform to improve access, quality, and system efficiency, providing a supportive regulatory and reimbursement environment that sustains market growth across the forecast period. Frost & Sullivan independently analyzed the information it collected, and the reliability of the Frost & Sullivan Report may be affected by the accuracy of the foregoing key assumptions.

The real-world data supporting the long-term safety and efficacy of aflibercept is predominantly generated by independent third parties. See "Business — Our Drug Candidates — Our Ophthalmic Drug Candidates".