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OVERVIEW

We are a China-based biotechnology company in the oncolytic virotherapy space, dedicated to the discovery, development, and commercialization of innovative cancer immunotherapies. We have internally developed our Core Product BS001 (OH2 Injection), a novel HSV-2-based oncolytic virus candidate, which is poised as the world’s first herpes simplex virus type 2 (HSV-2)-based oncolytic virus candidate to reach clinical stage and advance into a Phase III pivotal trial, underscoring its potential to become the first approved HSV-2-based oncolytic virotherapy globally. Our pipeline further includes two key product candidates, BS006 and BR003, along with additional candidates in clinical and preclinical development.

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The following chart illustrates our pipeline and summarizes the development status of each candidate as of the Latest Practicable Date, all of which are in-house discovered:

Platform	Candidate	Target	Administration	Structure	Indication	Regimen	Regulatory Authority	Preclinical	Phase I	Phase II	Phase III	BLA	Next Milestone	Commercial Rights	R&D Model
Viral Vector Platform	BS001 	hGM-CSF	Intratumoral	HSV-2	Unresectable or relapsed/metastatic melanoma (3L+)	Mono	NMPA FDA ⁽¹⁾	 The first to be included in the CDE's Breakthrough Therapy Designation ⁽²⁾ The first to receive both FDA Orphan Drug Designation and FDA Fast Track Designation ⁽³⁾					Expected 2026Q4 completion of Phase II clinical trial	Global	Self-developed
			Intratumoral (incl. metastatic lesion injection)	HSV-2	Unresectable or relapsed/metastatic CRC (2L+) ⁽⁴⁾	Combo with PD-1 inhibitor	NMPA FDA ⁽¹⁾						Expected 2026Q2 initiation of Phase II clinical trial		
			Intracavitary (via Omaya reservoir)	HSV-2	Relapsed GBM (1L+)	Mono	NMPA FDA						Expected 2026Q3 initiation of Phase II clinical trial		
			Intratumoral	HSV-2	Unresectable or relapsed/metastatic STS (2L+) ⁽⁵⁾	Combo with PD-1 inhibitor	NMPA FDA	 The first to receive FDA Orphan Drug Designation ⁽⁶⁾					Expected 2027Q2 initiation of Phase II clinical trial		
			Intratumoral (incl. metastatic lesion injection)	HSV-2	Unresectable or relapsed/metastatic BTC (2L+) ⁽⁵⁾	Combo with PD-1 inhibitor	NMPA FDA						Expected 2027Q4 initiation of Phase II clinical trial		
													Expected 2028Q2 initiation of Phase II clinical trial		
Nucleic Acid Delivery Platform	BS006 	PD-L1/ CD3 (TCE)	Intratumoral	HSV-2	Solid Tumors (2L+)	Mono	NMPA FDA						Expected 2026Q2 initiation of Phase I clinical trial	Global	Self-developed
	BR003 	IL-2 analog	Intravenous	LNP	Advanced Solid Tumors	Mono	NMPA/FDA						Expected 2026Q3 completion of IND application	Global	Self-developed
	BS051	Viral Nucleic Acid	Intravenous	LNP	Solid Tumors	Mono	NMPA/FDA						Expected 2027Q4 submission of IND application	Global	Self-developed

★ Core Product ▲ Key Product

Abbreviations: BLA = biologics license application; BTC = biliary tract cancer; CD3 = cluster of differentiation 3; CDE = Center for Drug Evaluation; Combo = combination therapy; CRC = colorectal cancer; FDA = Food and Drug Administration; GBM = glioblastoma; hGM-CSF = human granulocyte-macrophage colony-stimulating factor; HSV-2 = herpes simplex virus 2; IL-2 = Interleukin-2; IND = investigational new drug; LNP = lipid nanoparticle; Mono = monotherapy; NMPA = National Medical Products Administration; PD-1 = programmed cell death protein 1; PD-L1 = programmed death-ligand 1; STS = soft tissue sarcoma; TCE = T-cell engager.

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Notes:

1. Leveraging promising early-stage clinical data from China, we engaged EOP2 meetings with the FDA and received clearance to proceed directly into Phase III trials for the treatment of melanoma and CRC in December 2024 and September 2025, respectively.
2. In February 2023, our Core Product, BS001, received a Breakthrough Therapy Designation from the CDE of China. The primary study endpoint of its Phase III trials is overall survival (OS).
3. In July 2022, BS001 was granted Orphan Drug Designation (ODD) by the FDA for the treatment of Stage IIb to Stage IV melanoma. This represented the first and only instance in which an oncolytic virus candidate independently developed in China received such a designation from the FDA. Subsequently, in June 2023, the FDA also granted Fast Track Designation (FTD) to BS001 for the treatment of unresectable Stage III or IV melanoma that is resistant to, or has progressed following, anti-PD-1 therapy. The indications for which BS001 has obtained FTD and ODD are subtype-specific and do not correspond to the full scope of our IND approvals or the patient populations defined in our clinical protocols. Rather, these designations reflect the FDA’s recognition of unmet medical need or rare disease status with respect to particular indications within our broader clinical development program.
4. BS001 is being evaluated in unresectable or relapsed/metastatic CRC, unresectable or relapsed/metastatic STS, and unresectable or relapsed/metastatic BTC under a basket trial design registered under the same CTR/NCT number. In addition to the aforementioned indications (e.g., melanoma, CRC, GBM, STS and BTC), we are actively advancing a broad clinical development program for BS001 across multiple solid tumor types.
5. In August 2025, BS001 in combination with a PD-1 inhibitor was granted FTD from the FDA in treating cancers with proficient mismatch repair/microsatellite stability (pMMR/MSS) colorectal cancer patients with liver metastases (CRCLM) that have progressed on at least three lines of prior therapy. The indications for which BS001 has obtained FTD and ODD are subtypespecific and do not correspond to the full scope of our IND approvals or the patient populations defined in our clinical protocols. Rather, these designations reflect the FDA’s recognition of unmet medical need or rare disease status with respect to particular indications within our broader clinical development program.
6. In February 2024, BS001 was granted ODD by the FDA for the treatment of malignant glioma, marking it as the first China-originated, HSV-2-based oncolytic virus candidate to receive such designation for this indication.

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Over the years, we have built our proprietary R&D infrastructure to continuously fuel our drug development initiatives, which centers on a viral vector platform and is supplemented by nucleic acid delivery and protein biologics platforms. In designing molecular structure of our oncolytic virus candidates, we strategically select HSV-2 as the viral vector for its superior innate oncolytic potency, syncytium-inducing ability, and richer set of antitumor signaling pathways, compared to conventional HSV-1. Leveraging our mechanistic insights and engineering capabilities, we have adopted a targeted engineering strategy that deletes the neurovirulent infected cell protein 34.5 (ICP34.5) and immunosuppressive infected cell protein 47 (ICP47), meanwhile inserting human granulocyte-macrophage colony-stimulating factor (hGM-CSF), thereby achieving a dual mechanism of localized tumor lysis and systemic immune activation. We have also made advancements in the lipid nanoparticle (LNP) delivery technology which facilitates systemic administration of oncolytic viruses with high efficiency and precision, thereby overcoming challenges associated with intravenous dosing. Furthermore, we have identified a proprietary baseline biomarker X, converting a simple blood test into a companion diagnostic that steers low-X patients toward BS001 monotherapy and high-X patients toward BS001 in combination with programmed cell death protein 1 (PD-1) blockade. This straightforward stratification helps pinpoint responsive patient populations, accelerate development timelines, and improve therapeutic outcomes for oncolytic virotherapy.

BS001 is the world’s first HSV-2-based oncolytic virus candidate to reach clinical stage and advance into a Phase III pivotal trial, underscoring its potential to become the first approved HSV-2-based therapy globally. Under IND approvals from both the NMPA and the FDA for advanced solid tumors, we are investigating BS001 both as a monotherapy and in combination with PD-1 inhibitors across selected solid tumor types. Consistent with industry practice, our current clinical efforts are primarily directed at later-line settings, and we intend to advance into earlier lines of therapy as clinical evidence accumulates. We are now evaluating BS001 in patients with 3L+ unresectable or metastatic melanoma, 2L+ unresectable or relapsed/metastatic colorectal cancer (CRC), 1L+ relapsed glioblastoma (GBM), 2L+ unresectable or relapsed/metastatic soft tissue sarcoma (STS), and 2L+ unresectable or relapsed/metastatic biliary tract cancer (BTC).

We have progressed BS001 into a Phase III clinical trial in melanoma in China, which is a randomized controlled trial that notably employs overall survival (OS), the gold-standard efficacy endpoint in oncology recognized by competent regulatory authorities, as the primary endpoint. Its completed Phase Ia/Ib trial reported a prolonged median overall survival (mOS) of 46.6 months. It also reported an objective response rate (ORR) of 34.48% in patients with advanced melanoma, and an even higher ORR of 42.1% in those resistant to PD-1 therapy. Building on our promising early-stage trial data, we received FDA clearance for a Phase III trial of BS001 for melanoma in the U.S. When administered as monotherapy, BS001 has also demonstrated therapeutic potential in GBM, with multiple patients showing positive responses in an early-stage Phase I/II trial.

BS001’s distinctive ability to remodel the tumor microenvironment enhances its synergy with other established modalities. For instance, intratumoral use upregulates immune checkpoints to prime patients for combination with checkpoint inhibitors. Co-administration with radiotherapy or chemotherapy amplifies immunogenic cell death, antigen release, and T-cell activation. We are currently investigating the combination regimens integrating BS001 and a PD-1 inhibitor in Phase II trials across a variety of indications including, among others, CRC, STS and BTC, leveraging its broad-spectrum antitumor efficacy. In particular, we received FDA clearance for the initiation of a Phase III trial targeting CRC in the U.S. in September 2025.

In recognition of BS001’s clinical profile, regulatory authorities have granted the program several notable designations. The CDE awarded BS001 Breakthrough Therapy Designation (BTD), making it the first oncolytic virus candidate to receive this designation in China. The FDA has granted Fast Track Designation (FTD) for two indications, namely monotherapy in unresectable stage III/IV melanoma that is resistant to or has progressed after PD-1 inhibitors, and combination with PD-1 inhibitors in proficient mismatch repair/microsatellite stability (pMMR/MSS) colorectal cancer patients with liver metastases (CRCLM) who have progressed on at least three prior lines of

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therapy. The FDA also granted Orphan Drug Designation (ODD) for stage III to IV melanoma and for malignant glioma, making BS001 the first China-originated oncolytic virus candidate to secure ODD from the FDA. These designations are indication- or subtype-specific and do not correspond to the full scope of our IND approvals or the targeted patient populations.

Among our oncolytic virus franchise, we are also actively advancing our Key Product, BS006. BS006 is a HSV-2-based oncolytic virus candidate that incorporates a triple-synergy antitumor mechanism through (i) the dual deletion of ICP34.5 and ICP47, (ii) a bispecific antibody designed to simultaneously bind programmed death-ligand 1 (PD-L1) on tumor cells and CD3 on T cells, redirecting and activating T cells while blocking PD-L1-mediated checkpoint signaling, and (iii) restricting bispecific antibody expression to the tumor site. By inducing direct tumor cell lysis, BS006 alters the tumor microenvironment and converts “cold” tumors into “hot” tumors that are more responsive to checkpoint blockade. Targeting refractory solid tumors, BS006 has shown preclinical efficacy against larger-volume tumors. BS006 has entered a Phase I clinical trial in the U.S., and become the world’s first TCE-expressing HSV-based oncolytic virus in clinical development. In China, it also received the investigational new drug (IND) approval from the NMPA in August 2025.

Beyond the oncolytic virus candidates, our product portfolio comprises the nucleic acid franchise exemplified by BR003 and BS051, as well as protein biologics. BR003, our Key Product, is an LNP-encapsulated interleukin-2 (IL-2) analog therapy that selectively binds to IL-2R β γ receptor complex and avoids toxic side effects caused by IL-2R α receptor binding, maintaining strong antitumor immune activity. Developed through our proprietary RACE[®] (Rapid, Amplified, Capless, and Economical) nucleic acid platform, this candidate is designed to address the limitations of traditional IL-2 treatments while leveraging a versatile LNP platform.

We have integrated CMC and manufacturing capabilities. Notably, we are the only company nationwide to hold a Category A drug production license for oncolytic virus drugs. Despite the inherent complexity of oncolytic virus processes, our proprietary technologies in vector construction, efficient purification, and concentration have enabled production with cost-efficiency, purity, and stability. Our GMP-compliant manufacturing facility in Ezhou, Hubei Province, currently provides sufficient capacity to meet clinical and early commercial demands. This capability reduces development timelines and production costs.

OUR COMPETITIVE STRENGTHS

A Biotech Company Dedicated to Novel Oncolytic Virus Therapies that Address Significant Clinical Needs in Tumor Treatment

We are an innovation-driven biotechnology company with a worldwide outlook. By concentrating on the discovery and development of oncolytic virus therapeutics, we aim to meet pressing, underserved clinical needs and to deliver proprietary, globally accessible cancer medicines that offer patients safer and more effective treatment options.

- **Remarkable clinical progress.** We are setting the pace in oncolytic virotherapy with remarkable clinical progress. According to Frost & Sullivan, we hold the fastest-advancing oncolytic virus pipeline in China. As of the Latest Practicable Date, we had secured nine IND approvals from NMPA and FDA for our lead assets spanning monotherapy and combination regimens. Our Core Product BS001 has progressed into Phase III for melanoma in China, positioning it as the world’s first HSV-2-based oncolytic virus candidate to reach clinical stage and advance into a Phase III pivotal trial. It was granted the FTD by FDA in unresectable stage III or IV melanoma that is resistant to, or has progressed after anti-PD-1 therapy, as well as when used in combination with a PD-1 inhibitor, in pMMR/MSS CRCLM that have progressed on at least three lines of prior therapy. In addition, our Key Product BS006 has entered Phase I in the U.S., making it the world’s first TCE-expressing HSV-based oncolytic virus in clinical development, and received IND approval from NMPA in August 2025.

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- **Pipeline featured by potentially differentiated candidates.** We have curated a pipeline across three franchises including oncolytic viruses, nucleic-acid therapeutics, and protein biologics. Our oncolytic virus candidates leverage a dual-knockout strategy resembling approved HSV-based therapies, deleting both ICP34.5 and ICP47 from wild-type HSV-2 to confine replication to tumor cells, restore antigen presentation, and enhance safety and potency. Unlike comparable candidates, BS001 is being evaluated with OS as its primary clinical readout, the gold-standard efficacy endpoint aligning with the most stringent regulatory standards. BS001 has demonstrated encouraging efficacy with a favorable safety profile across clinical trials. In melanoma, Phase Ia/Ib data indicated a one-year survival rate of 91.0% and two-year survival rate of 72.0%, with current mOS of 46.6 months and longest survival of 76.7 months in Phase Ia subjects. In CRC, the Phase II trial of BS001 in combination with pucotenlimab reported longest OS of 40.1 months, with mOS reaching 6.5 months in patients with high biomarker X levels compared to approximately 3–4 months in external controls. Although administered intratumorally, BS001 elicits systemic immunity with 40% of non-injected lesions shrinking or stabilizing, underscoring its abscopal potential.
- **Large Market opportunity presented by pan-tumor indications.** The global oncolytic virus market is forecasted to soar from US\$87.1 million in 2024 to US\$7.55 billion by 2030; China’s oncolytic virus market is expected to leap from RMB45.3 million to RMB9.21 billion over the same period, according to Frost & Sullivan. Our HSV-2-based oncolytic virus candidates are being developed for a broad spectrum of hard-to-treat, late-stage cancers including, among others, melanoma, CRC, GBM, STS, and BTC, where effective options are scarce and prognosis remains poor, to capture such market opportunities.
- **Proprietary biomarker-driven precision.** Oncolytic virotherapy has long lacked a clinically validated biomarker to guide treatment. Biomarker X is a baseline biomarker identified by us in the clinical development of BS001. Based on the clinical data available to date, biomarker X has shown a correlation with OS and progression-free survival (PFS). In the relevant clinical observations, patients with lower biomarker X levels demonstrated higher response rates and disease control rates with BS001 monotherapy, while patients with higher biomarker X levels demonstrated improved clinical outcomes with BS001 in combination with a PD-1 inhibitor as compared with BS001 monotherapy. Among patients with higher biomarker X levels, combination therapy was associated with longer mOS and higher ORR and disease control rate (DCR) in the relevant study population. We believe biomarker X may have potential utility in supporting patient stratification and regimen selection in the clinical development of BS001.
- **Proprietary drug delivery platform.** Our self-developed LNP system is designed to encapsulate therapeutic payloads or oncolytic viral nucleic acids for systemic administration. This platform is intended to support intravenous delivery, thereby reducing the dependence on local injection. It also allows for surface chemistry modification to support tissue-targeting strategies. In addition, the platform has been developed to facilitate manufacturing and scale-up.

We are expanding our international clinical development activities and ramping up commercialization efforts to maximize the value of our product portfolio. Leveraging clinical data from China, our BS001 received FDA clearance to proceed directly into Phase III trials for the treatment of melanoma and CRC in December 2024 and September 2025, respectively. Building on our U.S. presence, we intend to expand clinical development into additional countries and regions, either independently or through strategic partnerships, to support potential future commercialization in multiple markets. On the commercialization front, we intend to enter into commercial collaborations with established domestic and global pharmaceutical leaders experienced in pharmaceutical distribution and sales, while concurrently building in-house workforce for timely product launches and deepened market penetration.

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Proprietary Technology Platforms Leading to Differentiated Backbone and Payload Design

At the core of our ongoing R&D activities lie our three proprietary and complementary technology platforms, including the viral vector platform, nucleic acid delivery platform, and protein biologics platform, through which we have advanced a pipeline of oncolytic virus candidates and other investigational agents.

- **Viral vector platform.** Our viral vector platform encompasses the design, development, and large-scale production of diverse backbones including HSV, adenovirus, and poxvirus. In selecting viral backbones, HSV exhibits resistance to neutralizing antibodies and larger capacity for foreign cytokine insertion compared to other virus types. According to a comprehensive meta-analysis published by *Lancet* examining 186 studies with 6,979 participants, Herpesviridae-based therapies demonstrated superior safety and efficacy profiles, with HSV exhibiting the lowest incidence of severe adverse events at 1.35% and Surface Under the Cumulative Ranking Curve (SUCRA) analysis identifying Herpesviridae-based combination therapy as the most effective approach for both ORR (87.70%) and DCR (78.20%). Among HSV types, HSV-2 demonstrates better oncolytic activity than HSV-1 owing to its ability to interfere with host antiviral defenses, facilitate natural killer (NK) cell-mediated tumor killing, induce syncytia formation, and activate diverse antitumor signaling pathways. We are positioned as the sole producer of HSV-2-based clinical-stage oncolytic virus candidates globally, having mastered production and purification technologies to achieve high-yield, high-purity virus at low cost. Our backbone modification features deletion of ICP34.5 and ICP47 to enhance tumor selectivity and promote antigen presentation, and insertion of hGM-CSF to activate cytotoxic T lymphocytes (CTLs) and NK cells. This design is consistent with the engineering strategy adopted by approved oncolytic virus therapies, including approved HSV-based oncolytic virus products, while reducing pathogenicity and promoting systemic antitumor immunity.
- **Nucleic acid delivery platform.** Our RACE[®] nucleic acid delivery platform is based on a proprietary lipid nanoparticle (LNP) system designed to overcome conventional delivery limitations including intravenous delivery barriers, immunogenicity, and restricted tissue targeting, enabling systemic administration of therapeutic and viral nucleic acid payloads. Three core innovations underpin the platform. First, a cap-free nucleic acid architecture replaces the conventional 5' cap with an internal ribosome entry site (IRES) element and uridine triphosphate (UTP) substitutes for chemically modified nucleotides, streamlining *in vitro* transcription and enhancing cost efficiency. Second, our bespoke lipid delivery system fabricated via automated microfluidic mixing yields 70–120 nm particles with polydispersity indices ≤ 0.3 and encapsulation efficiencies exceeding 90%, scaling to produce over 100,000 doses per batch. Third, extensive good laboratory practice (GLP) compliant toxicology studies demonstrated favorable tolerability with no severe systemic toxicities, no central nervous system (CNS) or respiratory effects, and a wide safety margin against hemolysis, providing strong validation for advancement into human clinical trials.
- **Protein biologics platform.** Complementing the viral vector and nucleic acid delivery platforms, our protein biologics platform integrates innovative expression technologies with next-generation purification systems to deliver high productivity, safety, and scalability. This platform rests on two core pillars: (i) a prokaryotic cell-free protein expression system that enables the rapid synthesis of structurally complex proteins, and (ii) a trimer-tag rapid purification technology that achieves efficient recovery of high-purity (>97%) proteins. Together, these capabilities not only accelerate internal R&D but also support the development of therapeutic proteins and vaccines for diverse clinical applications.

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Collectively, these three technology platforms operate under a cohesive model, enabling an integrated R&D process from vector construction to delivery optimization and functional enhancement, as well as horizontal synergy in which nucleic acid technologies refine administration modes for viral and protein therapeutics, and cell and protein innovations amplify the immunomodulatory potency of our oncolytic virus therapeutics.

BS001 (OH2 Injection): A Differentiated Oncolytic Virus with a Favorable Safety Profile, Broad Therapeutic Potential, and Distinct Combination Advantages Across a Growing Market

We are pioneering the oncolytic virus drug development in China. Our Core Product, BS001 (OH2 Injection), is poised as the world’s first HSV-2-based oncolytic virus candidate to reach clinical stage and to advance into a Phase III pivotal trial. It is also the first China-originated oncolytic virus to earn BTX from the CDE and both ODD and FTD from the FDA in targeted indications. These regulatory milestones underscore this candidate’s intrinsic strengths, such as its precise tumor selectivity, potent hGM-CSF-driven immune activation and exemplary safety profile.

BS001 is built on an HSV-2 backbone engineered with a dual-knockout strategy—deletion of the neurovirulent ICP34.5 to attenuate pathogenicity and sharpen tumor-selective replication, and removal of the immunosuppressive ICP47 to unmask antigen presentation and sustain oncolytic activity. This rational, precise engineering mirrors the design of approved HSV-based therapies, such as T-VEC, and fundamentally enhances BS001’s druggability by optimizing its safety profile, improving tumor targeting, and facilitating adaptive immune priming. To further amplify antitumor efficacy, BS001 incorporates a recombinant hGM-CSF cytokine that recruits and activates granulocytes, macrophages, cytotoxic T lymphocytes and NK cells, driving both local tumor lysis and systemic immune responses.

BS001 has demonstrated a consistently favorable safety profile across multiple solid tumor indications in both preclinical studies and clinical trials. In particular, as of June 27, 2025, among 421 patients treated with BS001, 75.06% experienced treatment-related adverse events (TRAEs), yet only 10.69% were Grade ≥ 3 and serious adverse reactions were limited to 4.76%, and discontinuations due to adverse events (AEs) in a mere 1.4%. No treatment-related deaths were reported, and no new or unexpected safety signals emerged, underscoring the therapy’s manageable risk profile.

BS001 combines potent single-agent activity with exceptional combination versatility. As a monotherapy, intratumoral BS001 not only induces direct tumor cell lysis but also alters the microenvironment, by upregulating PD-1, PD-L1, NKG2A and HLA-E, releasing neoantigens, and intercepting resistance pathways such as NF- κ B and PI3K/AKT, while maintaining an excellent safety profile dominated by mere Grade 1–2 adverse events. In combination regimens, BS001 converts immunologically “cold” tumors into “hot” lesions, enhancing T-cell infiltration and checkpoint target expression to potentiate anti-PD-1 therapies. When paired with chemotherapy, virus-induced cytotoxicity is heightened by nucleic acid damage, selective depletion of regulatory T cells and myeloid-derived suppressor cells (MDSCs) fosters viral spread, and apoptotic and resistance pathways are counteracted to improve chemosensitivity. Collectively, this dual capacity of BS001, as a powerful standalone oncolytic agent and as a versatile partner for established modalities, enables it to deliver comprehensive, multifaceted antitumor responses across cancer indications with substantial clinical needs.

BS001 exhibits broad-spectrum antitumor efficacy across a variety of indications, particularly in refractory or high-incidence cancers. Unlike many comparable programs that rely on surrogate measures, the BS001 trial design adopts OS, the gold-standard efficacy endpoint, as its primary readout. This choice signals our commitment to demonstrate durable clinical benefit and positions the study to satisfy the most stringent expectations of global regulators. We are currently evaluating the therapeutic potential of this candidate in a randomized controlled Phase III pivotal trial in China for unresectable or metastatic melanoma after failure of two or more prior therapies, as well as comprehensive Phase I and Phase II trials in China targeting unresectable or relapsed/metastatic

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CRC, relapsed GBM, unresectable or relapsed/metastatic STS, and unresectable or relapsed/metastatic BTC, among others. Notably, leveraging promising early-stage clinical data from China, we received clearance from the FDA through End-of-Phase 2 (EOP2) meetings for our Phase III clinical development plans for BS001, including a Phase III trial of BS001 monotherapy in melanoma, as well as a Phase III trial of the combination therapy of BS001 and a PD-1 inhibitor in unresectable or relapsed/metastatic CRC. As of the Latest Practicable Date, only four oncolytic virus therapies have been approved globally, with relatively limited labeled indications; whereas BS001’s rapid clinical progression underscores its potential to dramatically broaden the therapeutic scope of this modality. As oncolytic virus R&D and manufacturing technologies continue to advance, we anticipate further indication expansions and regulatory filings that will position BS001 at the forefront of the oncolytic virotherapy market. For details of market opportunities in each indication, see “Industry Overview—Overview of Oncolytic Virus Market.”

An Experienced R&D Team and Proprietary Technology Platforms Driving Clinical Progress Across Our Pipeline

We have established a comprehensive R&D system covering the full lifecycle of oncolytic virus and other investigational therapeutics, including mechanism studies, preclinical research (pharmaceutical, pharmacological, and toxicological studies), process development, quality management, clinical trials, and regulatory affairs. Our R&D functions are fully integrated, enabling the efficient advancement of our drug development programs.

Our Founder, Dr. Liu Binlei, possesses extensive expertise in oncolytic virus drug development. See “Business—Research and Development—Our in-house R&D team” for details. Building on years of clinical research practice, we have developed three proprietary technology platforms, including the viral vector platform, nucleic acid delivery platform, and protein biologics platform. Leveraging these platforms, we have advanced our current pipeline of lead candidates and laid a solid foundation for the future discovery and development of new therapeutic agents.

We have assembled an experienced R&D team dedicated to sustained innovation in the oncolytic virus field. As of the Latest Practicable Date, our R&D team comprised 64 personnel, of whom 28 individuals, representing approximately 44%, held master’s or PhD degrees, primarily in medical science, pharmacology, biology and chemistry. Our core team members have, on average, over 20 years of experience in new-drug R&D or quality management at multinational pharmaceutical companies or leading research institutions. They bring expertise across the spectrum of drug development, including preclinical research, process development, quality management, clinical research, and regulatory affairs, ensuring efficient advancement of our pipeline while mitigating development and approval risks.

In contrast to many other companies that fully outsource clinical trials to contract research organizations (CROs), we maintain our own in-house clinical management team. This enables us to design clinical trial protocols internally, directly communicate with physicians, and make timely protocol adjustments based on investigator feedback. Such direct oversight enhances the quality of clinical data collection, reduces CRO expenditure, and allows us to access first-hand patient data in a compliant manner. These data are further analyzed to generate insights that inform ongoing clinical research and subsequent drug development.

Since our establishment, we have received multiple national-level recognitions, including designation as a National High-Tech Enterprise (高新技術企業) and a National “Specialized, Refined, Differential, and Innovative Little Giant” Enterprise (專精特新「小巨人」企業). Our technology has also been widely acknowledged by government authorities. In 2018, we served as a project undertaker under the National Major Science and Technology Project for “Significant New Drug Development” (國家重大新藥創制科技重大專項), through which we systematically advanced the preclinical and clinical studies of BS001. In 2023, we again served as a project undertaker under the National Key Research and Development Program “Frontier Biotechnology” initiative (國家重點研發計劃前沿生物技術重點專項), where we were responsible for critical tasks including systemic

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delivery technologies for oncolytic viruses, new drug development, and clinical research of oncolytic virus therapies for solid tumors. We have also undertaken other national research initiatives, including projects under the National High-Tech R&D Program (Program 863) (國家高技術研究發展計劃 (863計劃)) and those funded by the National Natural Science Foundation of China (國家自然科學基金). Moreover, in 2025, we undertook a project under the National Major Science and Technology Project for Innovative Drug Development (創新藥物研發國家科技重大專項) administered by the China National Center for Biotechnology Development (中國生物技術發展中心).

Our proprietary drug candidates and platform technologies are safeguarded by a patent portfolio, which comprises 15 issued patents in China, 2 issued patents in the U.S., 1 issued patent in other jurisdictions, as well as 11 pending patent applications, including 7 in China, 4 in the U.S., as of the Latest Practicable Date.

CMC and Manufacturing Capabilities to Meet Pipeline Needs and Enable Efficient Production

Our comprehensive platform unifies process development, impurity profiling, analytical method validation, and stability testing, giving us full control from R&D through GMP manufacturing and quality release. HSV-2 manufacturing is inherently more complex than HSV-1 and other viral platforms, as the serotype replicates more slowly, releases more host-cell nucleic acid, and requires tighter coordination of large-scale culture, multi-step purification, and rigorous release testing. We have overcome these hurdles with proprietary high-yield, high-purity processes, establishing technical barriers that are difficult to replicate. Our purification processes are tailored to HSV-2 characteristics and composite chromatographic media to achieve effective separation of virus from host proteins, host nucleic acid, and medium components, enhancing viral purity and activity while mitigating quality and safety risks.

We operate GMP-compliant cleanroom facilities in Ezhou, Hubei Province with six independent production lines that flex from small batches to full-scale runs. Based on current virus titer (7.0 log CCID₅₀/mL, 1 mL/vial), our annual commercial production capacity can reach approximately 700,000 vials, sufficient to support both clinical research and early commercialization demands. In August 2023, we secured a Category A Drug Manufacturing License for therapeutic biologics from Hubei Provincial Medical Products Administration, making us the only company nationwide to hold such license for oncolytic virus drugs. This license authorizes us to manufacture innovative viral-vector drugs entirely in-house, subject to obtaining requisite marketing authorization and satisfying all relevant regulatory requirements.

Our in-house CMC framework reduces development and production costs. We have established our own production seed system including viral seed stocks and cell banks, minimizing reliance on third-party technologies and reducing licensing costs. Utilizing the intrinsic characteristics of oncolytic virus therapies, namely lower dosing frequency and self-replication capacity, we are able to produce sufficient quantities with only a limited number of small-scale bioreactors, reducing fixed capital requirements.

Top-tier Management Team with Global Vision and Deep Medical Expertise, Supported by Prominent Investors

Our leadership team brings together global perspective, clinical depth, and extensive management experience across the full lifecycle of drug development, from discovery, manufacturing to commercialization. The combination of a visionary founder, an experienced management team, and the backing of blue-chip investors lays a solid foundation to expand our market presence and elevate our global competitiveness.

At the helm of our Company is Dr. Liu Binlei, our founder, chairman of our Board, executive Director and general manager, who brings over 30 years of expertise in tumor immunology and oncolytic viruses. Dr. Liu previously worked at BioVex Inc., a UK-based biopharmaceutical company, where he served as a postdoctoral research scientist, senior scientist and later as molecular

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biology group leader. During his tenure at BioVex, Dr. Liu was pivotal in the development of T-VEC, the first oncolytic virus therapy to receive FDA approval. As a core member of the original R&D team, Dr. Liu was responsible for producing much of the preclinical package for T-VEC. His work established the mechanistic basis for T-VEC, and enabled its preclinical validation and completion of the IND-enabling studies. Specifically, Dr. Liu identified JS-1 as the optimal HSV-1 parental backbone through systematic screening, and established an HSV-1 oncolytic virus engineering platform that enabled the construction of multiple therapeutic viral variants. His *in vitro* studies had demonstrated T-VEC’s potent oncolytic activity across multiple tumor cell lines while confirming selective replication in malignant versus normal cells. His *in vivo* studies had established the anti-tumor efficacy of T-VEC, demonstrating direct tumor lysis, immune activation, and durable anti-tumor memory. Dr. Liu also led the design and integration of the preclinical studies required for IND submission, including drafting key pharmacology and mechanism-of-action components and responding to regulatory queries. By the time of Dr. Liu’s departure in 2009, T-VEC had already advanced into clinical development, with Phase I trials having been initiated in 2006. During the clinical phase, Dr. Liu oversaw genomic sequencing and characterization of T-VEC, which confirmed that T-VEC maintained a stable genome with no evidence of pathogenic reversion, thereby reinforcing the product’s safety profile and supporting its continued clinical advancement. Dr. Liu’s multiple peer-reviewed publications related to oncolytic virus or T-VEC preclinical research also demonstrate his significant contributions to the T-VEC development program when he was at BioVex. For example, in 2003, Dr. Liu published a first-author paper in *Gene Therapy* (a Nature journal) entitled “ICP34.5 deleted herpes simplex virus with enhanced oncolytic, immune stimulating, and anti-tumour properties.” This article was selected for inclusion in the journal’s “25 Years of Gene Therapy” collection, which featured 25 landmark papers highlighting the journal’s most significant contributions to the field between 1997 and 2019.

Beyond T-VEC, he also led the design, construction, and preclinical testing of a suite of innovative HSV-1 vectors incorporating immunomodulatory molecules. Under his leadership, our R&D team has built a proprietary oncolytic HSV-2 platform and successfully executed multiple national scientific programs, including the National Major Science and Technology Project for “Significant New Drug Development” (國家重大新藥創製科技重大專項), the National Key Research and Development Program “Frontier Biotechnology” initiative (國家重點研發計劃前沿生物技術重點專項), the National High-Tech R&D Program (Program 863) (國家高技術研究發展計劃(863計劃)), and projects funded by the National Natural Science Foundation of China (國家自然科學基金). Moreover, in 2025, we undertook a project under the National Major Science and Technology Project for Innovative Drug Development (創新藥物研發國家科技重大專項) administered by the China National Center for Biotechnology Development (中國生物技術發展中心).

Our management team is further bolstered by key members with decades of collective experience at leading multinational pharmaceutical companies and research institutions both in China and abroad. For instance, Mr. Fang Zhizheng, our Executive Director and deputy general manager, brings approximately 40 years of hands-on experience in process development and large-scale biomanufacturing, and is currently responsible for overseeing the manufacturing of our Group. Mr. Wang Hanming, our Executive Director and deputy general manager, offers extensive regulatory registration know-how and proven success in translating candidates from clinic to market, and is currently responsible for overseeing the clinical affairs of our Group. Leveraging this blend of industrial heritage and multinational best practices, we’ve built a robust process and quality management system that underpins efficient, compliant operations from R&D through commercial launch. Over years of dedicated effort, this sophisticated governance framework ensures seamless execution across product development, manufacturing, and market delivery.

Our drug candidates have garnered strong endorsements from leading industry investors such as Lepu Biopharma, Yangtze River Pharmaceutical Group, and Jointown Pharmaceutical Group. We have also attracted capital support from renowned domestic and international institutions including Lapam Investment, Share Capital, CICC Capital, Qianhai FoF, Vertex Investment, Fortune Capital, Optics Valley Venture Capital, Chang’an Capital, Infinity Equity, and ZBJL

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Capital. Supported by this blend of leadership, industry expertise, and financial backing from prominent shareholders, we are exceptionally well positioned to deepen our market presence and accelerate our global expansion.

OUR STRATEGIES

Accelerating the Global Clinical Development and Commercialization of Our Core Product BS001 and Key Product BS006 Across Multiple Indications

We have prioritized BS001 for indications with substantial clinical needs including among others, unresectable or metastatic melanoma, unresectable or relapsed/metastatic CRC, relapsed GBM, unresectable or relapsed/metastatic STS, and unresectable or relapsed/metastatic BTC, and are executing adaptive clinical development strategy for each.

- *Melanoma.* BS001 has advanced into a Phase III clinical trial for the treatment of unresectable or metastatic melanoma in China in March 2023, with two-thirds of patient enrollment nearly completed as of March 5, 2026. The interim data readouts for this trial are expected in the third quarter of 2026, following which we plan to submit the biologics license application (BLA) to the NMPA in the fourth quarter of 2026. In the U.S., we engaged an EOP2 meeting with the FDA and received clearance for a Phase III trial of BS001 targeting melanoma in the U.S., which we expect to initiate in the fourth quarter of 2026.
- *CRC.* We completed a Phase I/II trial of BS001 in combination with pucotenlimab (PD-1 inhibitor) for the treatment of unresectable or relapsed/metastatic CRC in China in January 2024. Subject to regulatory communications with the CDE, we plan to commence a Phase III trial in China in the second quarter of 2026. In parallel, we received the FDA clearance through an EOP2 meeting in September 2025 for a Phase III trial of the same combination regimen targeting CRC in the U.S., which we expect to initiate in the fourth quarter of 2026.
- *GBM.* We completed the Phase I part of a combined Phase I/II trial of BS001 in patients with relapsed GBM in China in November 2023, and fully enrolled the Phase II cohort in June 2025. We expect to initiate the Phase III clinical trial in the third quarter of 2026. In the U.S., we plan to leverage our established early-stage trial data to proceed directly to a Phase II trial, with anticipated commencement in the fourth quarter of 2026.
- *STS.* We conducted the Phase II evaluation of a combined Phase I/II trial of BS001 in combination with pucotenlimab (PD-1 inhibitor) for the treatment of unresectable or relapsed/metastatic STS in China in January 2024. We are also considering expanding the Phase II clinical program to gather a more comprehensive clinical dataset to inform the design of subsequent registrational study. We expect to initiate a Phase III trial targeting the same in China as early as the second quarter of 2027. In the U.S., we expect to initiate a Phase II trial of BS001 in combination with a PD-1 inhibitor in STS in the fourth quarter of 2027.
- *BTC.* We conducted the Phase II evaluation of a combined Phase I/II trial of combination therapy integrating BS001 and pucotenlimab (PD-1 inhibitor) for unresectable or relapsed/metastatic BTC in China in January 2024. We are also considering expanding the Phase II clinical program to gather a more comprehensive clinical dataset to inform the design of subsequent registrational study. We expect to initiate a Phase III trial targeting BTC in China as early as the fourth quarter of 2027. In the U.S., we expect to initiate a Phase II trial for the same combination regimen in the second quarter of 2028.

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We are concurrently advancing BS006, a next-generation HSV-2-based oncolytic virus engineered to locally express a PD-L1/CD3 bispecific TCE. BS006 has entered a Phase I clinical trial in patients with advanced or metastatic solid tumors in the U.S., with anticipated completion in the fourth quarter of 2026. In China, it also received the IND approval from the NMPA in August 2025, and we plan to initiate a Phase I clinical trial in the second quarter of 2026.

Innovating Drug Delivery to Broaden Therapeutic Applications

To overcome limitations associated with conventional routes of administration, we are developing multiple delivery approaches for specific tumor types and anatomical contexts. Our strategic delivery framework comprises of three tiers, including intratumoral injection as the gold standard, alternative local administration modalities tailored to each indication, and LNP-enabled intravenous delivery for systemic reach.

Traditional Intratumoral Injection

Intratumoral injection is a localized treatment method involving precise injection of therapeutic agents directly into the tumor, an established approach for FDA-approved oncolytic virus T-VEC and the primary route for most oncolytic virus candidates in development. We employ intratumoral injection for tumors accessible via percutaneous routes, such as melanoma, soft tissue sarcoma, and certain advanced gastrointestinal cancers. This method achieves peak local drug concentrations that maximize tumor cell destruction and activate tumor-draining lymph nodes to sustain robust immune response while minimizing systemic exposure. We have standardized injection protocols that mitigate procedural risks including tissue injury, infection, and potential tumor cell dissemination.

Intraventricular Administration Represented by Ommaya Reservoir

Beyond traditional intratumoral delivery, we explore additional local administration strategies based on tumor types. For intracranial malignancies such as glioblastoma (GBM), we employ intraventricular delivery via an Ommaya reservoir, implanting a subcutaneous port connected to cerebrospinal fluid (CSF) to achieve uniform leptomeningeal distribution and enable real-time biomarker monitoring through serial CSF sampling. In conjunction with interventional radiology, we develop catheter-based approaches for organ-confined lesions and investigate regional perfusion techniques such as isolated limb or hepatic artery infusion to concentrate therapeutics in target tissues. These modalities expand treatment options for tumors inaccessible by percutaneous injection, delivering high local drug exposure with minimal systemic toxicity.

Intravenous Administration Optimized by Proprietary LNP Delivery System

To address disseminated and deep-seated tumors beyond the reach of local routes, we have developed a proprietary LNP delivery platform for intravenous administration of therapeutic payloads or viral nucleic acids. By leveraging the inherent advantages of LNPs such as low immunogenicity, excellent biocompatibility, and reduced probability of clearance by the innate immune system, we preserve therapeutic efficacy following intravenous administration. Our proprietary LNPs leverage antibody conjugation, polyethylene glycol conjugation (PEGylation), and surface-charge engineering to extend systemic half-life and selectively accumulate in tumor tissues. The modular nature of this platform makes it adaptable for diverse oncolytic payloads across a broad spectrum of solid tumors.

Pursuing Strategic Global Partnerships to Accelerate Development and Commercialization

In China, we plan to implement a flexible, partnership-driven commercial model designed for rapid market penetration. We intend to collaborate with established domestic pharmaceutical companies, leveraging their extensive commercial infrastructure and proven market expertise in implementing “academic promotion + marketing” initiatives. Notably, we have reached collaboration with Lepu Biopharma to jointly evaluate BS001 combined with PD-1 and PD-L1 inhibitors, respectively, in Lepu Biopharma’s portfolio in Mainland China. The alliance affords us

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early access to clinically validated checkpoint-inhibitors, accelerating proof-of-concept for our lead asset at modest incremental cost, while both parties benefit from an expanded therapeutic portfolio, shared development risks, and enhanced pathways to potential combination regimens.

Internationally, we are proactively pursuing a dual-track strategy to bring our innovations to the global stage. We are engaging with the FDA on the clinical pathway for our Core Product, BS001, while simultaneously identifying and negotiating with major global biopharmaceutical partners. Our goal is to establish collaborations that leverage world-class expertise in late-stage development, manufacturing, and commercialization, ensuring an accelerated regulatory and market launch for our products worldwide.

Strengthening Talent Development and Organizational Culture

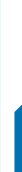
We are establishing a diversified evaluation system to identify and attract exceptional talent across key functional domains, including preclinical and clinical-stage R&D, pilot-scale production, and commercial manufacturing. With the support of strategic partners, we will dedicate increased resources and focus to develop more targeted selection criteria. Our goal is to recruit academic and commercial professionals at all levels who possess both high academic standards and substantial experience in the oncology sector, aligning with our technology promotion needs, while also identifying and nurturing high-potential candidates internally for focused development.

Furthermore, we are committed to continuously cultivating a cohesive and dynamic corporate culture that encourages and energizes innovation. We provide employees with competitive compensation, a refined performance evaluation system, and transparent career progression pathways. By encouraging participation in core company projects, we enable our team members to enhance both technical and managerial competencies, achieve personal value, and strengthen their sense of belonging and commitment to the organization.

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OUR PIPELINE

We have curated a pipeline spanning three strategic franchises, including oncolytic viruses, nucleic-acid therapeutics, and protein biologics. Each franchise is powered by proprietary platform technologies that enable us to advance innovative therapies from discovery through clinical development. By unifying our platform capabilities, we accelerate development timelines, reduce risk, and maximize the therapeutic potential of the entire portfolio. The chart below summarizes the development status of our in-house developed drug candidates as of the Latest Practicable Date:

Platform	Candidate	Target	Administration	Structure	Indication	Regimen	Regulatory Authority	Preclinical	Phase I	Phase II	Phase III	BLA	Next Milestone	Commercial Rights	R&D Model
Viral Vector Platform	BS001 	hGMCSF	Intratumoral	HSV-2	Unresectable or relapsed/metastatic melanoma (3L+)	Mono	NMPA FDA ⁽¹⁾		The first to be included in the CDE's Breakthrough Therapy Designation ⁽²⁾				Expected 2026Q4 completion of Phase II clinical trial Expected 2026Q4 initiation of Phase II clinical trial	Global	Self-developed
			Intratumoral (incl. metastatic lesion injection)	HSV-2	Unresectable or relapsed/metastatic CRC (2L+y) ⁽³⁾	Combo with PD-1 inhibitor	NMPA FDA ⁽¹⁾		The first to receive both FDA Orphan Drug Designation and FDA Fast Track Designation ⁽³⁾						
			Intracavitary (incl. Ovarian cysts resection)	HSV-2	Relapsed GBM (1L+)	Mono	NMPA FDA		The first to receive FDA Orphan Drug Designation ⁽³⁾				Expected 2026Q3 initiation of Phase II clinical trial Expected 2026Q4 initiation of Phase II clinical trial	Global	Self-developed
			Intratumoral	HSV-2	Unresectable or relapsed/metastatic STS (2L+y) ⁽³⁾	Combo with PD-1 inhibitor	NMPA FDA		The first to receive FDA Orphan Drug Designation ⁽³⁾				Expected 2027Q2 initiation of Phase II clinical trial Expected 2027Q4 initiation of Phase II clinical trial		
			Intratumoral (incl. metastatic lesion injection)	HSV-2	Unresectable or relapsed/metastatic BTC (2L+y) ⁽³⁾	Combo with PD-1 inhibitor	NMPA FDA		The first to receive FDA Orphan Drug Designation ⁽³⁾				Expected 2027Q4 initiation of Phase II clinical trial Expected 2028Q2 initiation of Phase II clinical trial	Global	Self-developed
			Intratumoral	HSV-2	Solid Tumors (2L+)	Mono	NMPA FDA		The first to receive FDA Orphan Drug Designation ⁽³⁾				Expected 2028Q2 initiation of Phase I clinical trial Expected 2028Q4 completion of Phase I clinical trial		
Nucleic Acid Delivery Platform	BS006 	PD-L1 / CD3 (TCE)	Intratumoral	HSV-2	Solid Tumors (2L+)	Mono	NMPA FDA		Expected 2026Q2 initiation of Phase I clinical trial Expected 2026Q4 completion of Phase I clinical trial				Global	Self-developed	
	BR003 	IL-2 analog	Intravenous	LNP	Advanced Solid Tumors	Mono	NMPA/FDA		Expected 2026Q3 completion of IND application				Global	Self-developed	
	BS051	Viral Nucleic Acid	Intravenous	LNP	Solid Tumors	Mono	NMPA/FDA		Expected 2027Q4 submission of IND application				Global	Self-developed	

★ Core Product ▲ Key Product

Abbreviations: BLA = biologics license application; BTC = biliary tract cancer; CD3 = cluster of differentiation 3; CDE = Center for Drug Evaluation; Combo = combination therapy; CRC = colorectal cancer; FDA = Food and Drug Administration; GBM = glioblastoma; hGM-CSF = human granulocyte-macrophage colony-stimulating factor; HSV-2 = herpes simplex virus 2; IL-2 = Interleukin-2; IND = investigational new drug; LNP = lipid nanoparticle; Mono = monotherapy; NMPA = National Medical Products Administration; PD-L1 = programmed cell death protein 1; PD-L1 = programmed death-ligand 1; STS = soft tissue sarcoma; TCE = T-cell engager.

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Notes:

1. Leveraging promising early-stage clinical data from China, we engaged EOP2 meetings with the FDA and received clearance to proceed directly into Phase III trials for the treatment of melanoma and CRC in December 2024 and September 2025, respectively.
2. In February 2023, our Core Product, BS001, received a Breakthrough Therapy Designation from the CDE of China. The proposed indication is for patients with unresectable or metastatic melanoma who have failed at least two prior lines of standard therapy. Standard treatment options include chemotherapy, radiotherapy, immunotherapy, and in patients with actionable mutations, targeted therapy. Adjuvant therapy completed within 6 months prior to progression, or disease progression during adjuvant therapy leading to unresectable or metastatic melanoma, can be considered as one prior line of therapy for advanced disease. The primary study endpoint is overall survival (OS).
3. In July 2022, BS001 was granted Orphan Drug Designation (ODD) by the FDA for the treatment of Stage IIb to Stage IV melanoma. This represented the first and only instance in which an oncolytic virus candidate independently developed in China received such a designation from the FDA. Subsequently, in June 2023, the FDA also granted Fast Track Designation (FTD) to BS001 for the treatment of unresectable Stage III or IV melanoma that is resistant to, or has progressed following, anti-PD-1 therapy. The indications for which BS001 has obtained FTD and ODD are subtype-specific and do not correspond to the full scope of our IND approvals or the patient populations defined in our clinical protocols. Rather, these designations reflect the FDA’s recognition of unmet medical need or rare disease status with respect to particular indications within our broader clinical development program.
4. BS001 is being evaluated in unresectable or relapsed/metastatic CRC, unresectable or relapsed/metastatic STS, and unresectable or relapsed/metastatic BTC under a basket trial design registered under the same CTR/NCT number. In addition to the aforementioned indications (e.g., melanoma, CRC, GBM, STS and BTC), we are actively advancing a broad clinical development program for BS001 across multiple solid tumor types.
5. In August 2025, BS001 in combination with a PD-1 inhibitor was granted FTD from the FDA in treating cancers with proficient mismatch repair/microsatellite stability (pMMR/MSS) colorectal cancer patients with liver metastases (CRCLM) that have progressed on at least three lines of prior therapy. The indications for which BS001 has obtained FTD and ODD are subtypespecific and do not correspond to the full scope of our IND approvals or the patient populations defined in our clinical protocols. Rather, these designations reflect the FDA’s recognition of unmet medical need or rare disease status with respect to particular indications within our broader clinical development program.
6. In February 2024, BS001 was granted ODD by the FDA for the treatment of malignant glioma, marking it as the first China-originated, HSV-2-based oncolytic virus candidate to receive such designation for this indication.

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Oncolytic Virus Franchise

We have developed a oncolytic virus pipeline based on our own viral vector platform, comprising our Core Product, BS001, and our Key Product, BS006. BS001, our Core Product, is a differentiated HSV-2-based oncolytic virus candidate with a favorable safety profile, broad therapeutic potential and distinct combination advantages across a growing market. BS006 is a next-generation HSV-2-based oncolytic virus candidate that incorporates a triple-synergy antitumor mechanism, including direct tumor cell lysis to alter the tumor microenvironment, local expression of a PD-L1/cluster of differentiation 3 (CD3) bispecific TCE to activate and redirect T cells, and concurrent blockade of PD-L1 signaling. Together, our advanced oncolytic virus portfolio, combined with deep expertise and proprietary platform technologies, drives development of a cocktail approach that leverages different oncolytic viruses, each armed with distinct therapeutic nucleic acid sequence, to broaden antitumor activity, mitigate resistance, and deliver more durable clinical benefits in solid tumors.

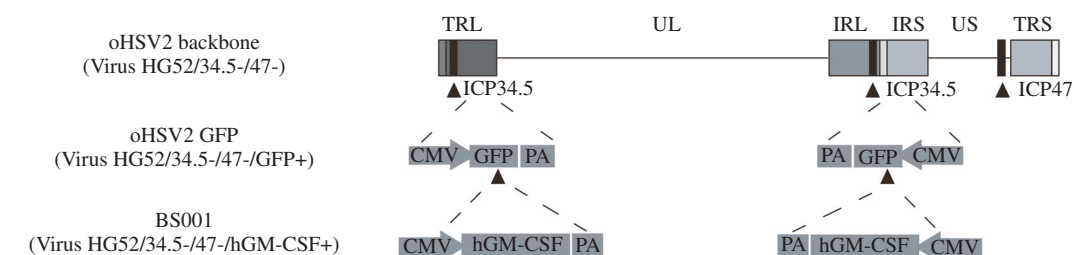
BS001 (OH2 Injection/rHSV2^{hGM-CSF})—our Core Product

Overview

BS001 (rHSV2^{hGM-CSF}) is a recombinant oncolytic herpes simplex virus type II (OH2) therapeutic injection (Vero Cell) exclusively developed by us for the treatment of advanced solid tumors. BS001 stands as the world’s first HSV-2-based oncolytic virus candidate to reach clinical stage and the first of its class to advance into a Phase III pivotal trial. It utilizes a novel viral vector offering enhanced replication and oncolytic potency compared to other conventional vectors. It is an attenuated oncolytic herpes simplex virus type 2 that was derived from the wild-type HSV-2 strain HG52. BS001 has been engineered with deletions of the ICP34.5 and ICP47 to enhance tumor selectivity and antigen presentation, and with insertion of the hGM-CSF cytokine to promote anti-tumor immune responses. BS001 can enhance the replication of the virus in tumor cells, resulting in the destruction of injected tumors, and enhance anti-tumor immunity.

BS001 has received IND approvals from both the NMPA and the FDA for advanced solid tumors. It has advanced into the Phase III pivotal stage for the treatment of unresectable or metastatic melanoma in China. In the U.S., we have obtained FDA clearance to proceed with Phase III trials of BS001 monotherapy for unresectable or relapsed/metastatic melanoma and BS001 in combination with a PD-1 inhibitor for unresectable or relapsed/metastatic CRC. Under the IND approvals, we are also evaluating this lead asset in a variety of clinical trials across various solid tumors, in which our BS001 has demonstrated a promising safety and encouraging efficacy profile. The diagram set forth below illustrates the stepwise engineering of the BS001 viral backbone derived from the HSV-2 HG52 strain, in which both copies of the neurovirulence ICP34.5 and the immunomodulatory ICP47 are deleted, followed by insertion of exogenous expression cassettes. In the intermediate green fluorescent protein (GFP)-tagged construct, a CMV-GFP-PA cassette for the expression of GFP is introduced at the deleted locus of ICP34.5, which is subsequently replaced in BS001 by CMV-hGM-CSF-PA cassettes to enable hGM-CSF expression.

BS001 Viral Backbone Engineering



Source: Company data

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Across a comprehensive cascade of clinical trials in different stages, BS001 has consistently demonstrated robust antitumor efficacy while maintaining an excellent safety and tolerability profile. Specifically,

- **Melanoma.** The Phase Ia/Ib clinical data as of August 15, 2025 demonstrated a one-year survival rate of 91.0% and a two-year survival rate of 72.0%. Our current mOS has reached 46.6 months. The longest survival observed in Phase Ia subjects was 76.7 months, markedly superior to historical benchmarks. In the same study, the ORR was 34.48%, and notably, among patients with immune resistance to PD-1 inhibitors, the ORR reached 42.1%, significantly outperforming historical controls. The trial population included 75% of patients with refractory acral lentiginous melanoma, a subtype that is more aggressive, less responsive to immunotherapy, and associated with poorer prognosis compared with the cutaneous subtype which is more common in Caucasian populations. According to Frost & Sullivan, BS001 has demonstrated improved overall safety and efficacy profile including ORR, DRR and mOS, as compared to the publicly available data of the approved product. The clinical trials of unresectable or metastatic melanoma are being conducted in China, and leveraging the results from these studies, we have obtained FDA clearance to initiate a Phase III trial in this indication in the U.S.
- **CRC.** In China, the Phase II clinical trial of BS001 in combination with pucotenlimab for unresectable or relapsed/metastatic CRC has been completed. The trial, which was completed in January 2024, showed that among subjects who had failed third-line therapy, of whom 71% had liver metastases, the longest OS reached 40.1 months, significantly superior to historical controls. In patients with high levels of biomarker X, median OS with BS001 in combination with pucotenlimab reached 6.5 months, compared with approximately 3–4 months in external controls for the same indication. Although administered intratumorally, BS001 has also demonstrated abscopal potential, with complete disappearance of one non-injected lesion and evidence of shrinkage or stabilization in other non-injected lesions. In September 2025, we held an EOP2 meeting with the FDA, which agreed that we can proceed with a Phase III trial of BS001 in combination with a PD-1 inhibitor for CRC in the U.S.
- **GBM.** According to the Phase I data as of September 10, 2024 from evaluable patients, the mOS reached 11 months and the ORR was 14.3%. The enrolled population primarily comprised relapsed patients with recurrent disease after secondary surgery, with a substantial baseline tumor burden as reflected by the mean tumor area at enrollment. Administered conveniently via an Ommaya reservoir, BS001 offers good patient adherence and operational ease, while overcoming the limitations of traditional administration methods, where intratumoral injections are restricted by accessibility and conventional intravenous injections suffer from low efficiency and poor targeting. According to Frost & Sullivan, its efficacy profile is similar to the other drug candidate currently most advanced in clinical stage.
- **STS.** Our BS001, in combination with pucotenlimab, shows clear competitive advantages in unresectable or relapsed/metastatic STS. The Phase II clinical trial in January 2024 showed that among 18 patients, of whom 44.4% had failed three or more prior lines of therapy, mOS reached 18.04 months, significantly superior to historical controls and the other drug candidate currently most advanced in clinical stage. Two cases of CR were also observed in this trial.

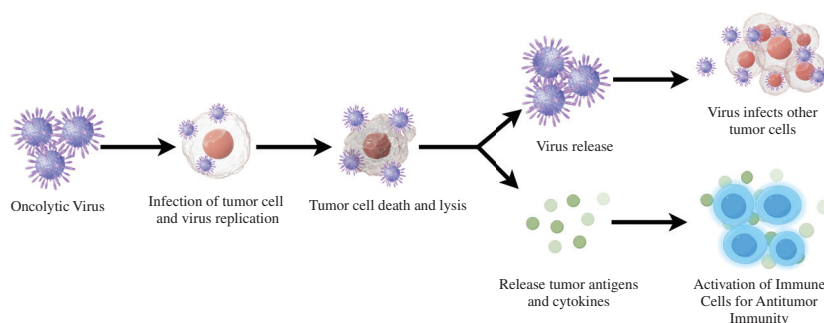
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- BTC. Our BS001, in combination with pucotenlimab, demonstrates competitive advantages in unresectable or relapsed/metastatic BTC. Phase II data showed that among subjects receiving late-line therapy, the longest OS reached 33.1 months, significantly exceeding historical benchmarks. In addition, one patient achieved a maximum reduction of 65% in the size of the target lesion.

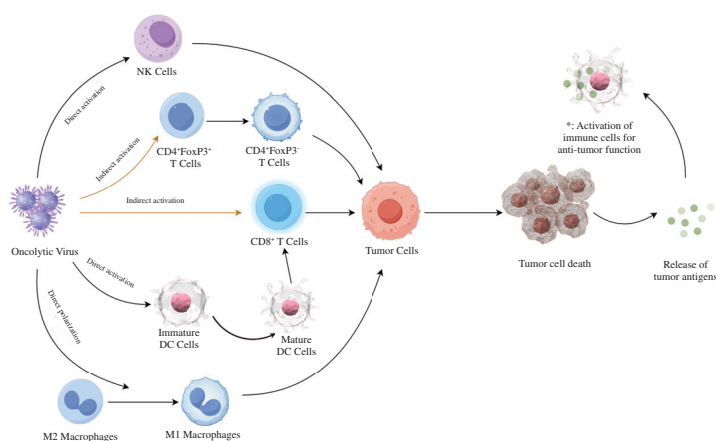
Mechanism of Action

Oncolytic virus therapy exerts its therapeutic effect through a dual mechanism of direct tumor cell lysis and immune-mediated anti-tumor responses. By selectively infecting and replicating within tumor cells, oncolytic viruses induce tumor cell lysis while largely sparing normal tissues. The lysis of tumor cells releases tumor-associated antigens together with viral pathogen- and damage-associated molecular patterns, which stimulate both innate and adaptive immune responses. This process converts immunologically “cold” tumors into “hot” tumors and triggers systemic anti-tumor immunity. The diagrams set forth below illustrates this process.

Mechanism of Action of Oncolytic Virus Therapy



Oncolytic Virus—Mediated Activation of Anti-Tumor Immunity



Sources: Company data, Frost & Sullivan Analysis

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BS001 is a modified oncolytic HSV-2 designed to enhance tumor selectivity, replication efficiency, and immune activation. The HSV-2 backbone adopted by BS001 also provides enhanced antitumor potency. The dual deletion of ICP34.5 and ICP47 restricts viral replication to tumor cells and restores antigen presentation, thereby improving both safety and efficacy, enhancing druggability, and providing a differentiated profile among oncolytic virus therapies. In addition, BS001 is armed with the hGM-CSF cytokine. The expression of hGM-CSF promotes the recruitment and activation of dendritic cells and T cells, which further enhances anti-tumor immune responses against both injected and distant lesions. This design integrates direct oncolytic activity with antitumor immune activation, thereby further enhancing the therapeutic potential of BS001 across multiple tumor types. Through this synergistic mechanism, BS001 combines tumor-selective replication, efficient antigen release and presentation, direct killing, and systemic anti-tumor immune responses. These attributes support its potential applicability across a broad range of solid tumors, including indications with historically poor response to existing immunotherapies, and provide a strong foundation for its advancement into late-stage clinical development.

Market Opportunity and Competition

Advances in oncolytic virus engineering, particularly armed and next-generation platforms, together with supportive regulatory initiatives and strong investor interest, are accelerating development and commercialization in this field. High needs in hard-to-treat tumors such as melanoma, CRC, and GBM provide clearly defined patient populations and reinforce the market’s rapid growth trajectory. According to Frost & Sullivan, the global oncolytic virus market increased from US\$43.6 million in 2020 to US\$87.1 million in 2024 (CAGR of 18.9%) and is projected to reach US\$7.5 billion by 2030, reflecting a CAGR of 110.4% from 2024 to 2030. In China, the market expanded from RMB23.8 million in 2020 to RMB45.3 million in 2024 (CAGR of 17.4%) and is expected to surge to RMB9.2 billion by 2030 (CAGR of 142.5%), marking a transition from early-stage development to rapid growth. As the only Phase III oncolytic virus candidate currently in China, BS001 is well positioned to address significant clinical needs, improve patient access, and establish a strong competitive advantage in the domestic market. See “Industry Overview—Overview of Oncolytic Virus Market”.

BS001 is advancing rapidly across multiple indications, including melanoma, GBM, CRC, STS, and BTC, all of which represent areas of substantial unmet medical need. By focusing on patients with advanced-stage disease lacking effective standard-of-care options, BS001 has the potential to offer new therapeutic alternatives for hard-to-treat cancers and to deliver meaningful improvements in patient outcomes upon approval and commercialization.

Globally, melanoma incidence increased from approximately 324.6 thousand cases in 2020 to 351.6 thousand in 2024 (CAGR of 2.0%) and is projected to reach 376.6 thousand by 2030. In China, incidence rose from 8.3 thousand in 2020 to 9.2 thousand in 2024 and are expected to reach 10.3 thousand by 2030. The melanoma therapeutics market is expected to maintain its upward trajectory in the near future. From 2024 to 2030, the global market is projected to grow from US\$18.5 billion to US\$24.0 billion, reflecting a CAGR of 4.5%. In China, the market is expected to expand from RMB2.0 billion to RMB3.1 billion over the same period, with a higher CAGR of 7.6%, driven by increasing diagnosis rates, broader access to innovative therapies, and growing awareness of subtype-specific treatment strategies. Although immune checkpoint inhibitors have improved outcomes, many patients exhibit primary resistance or relapse, and subtypes such as mucosal melanoma, acral melanoma, and melanoma brain metastases respond poorly. High rates of immune-related adverse events also limit their use in vulnerable patients. Given melanoma’s inherent immunogenicity, oncolytic virus therapy offers an alternative. BS001’s current target population includes patients with unresectable and/or metastatic or recurrent melanoma who meet clinical trial criteria for third-line therapy. The addressable population in 2024 was approximately 3.3 thousand in China and 101.0 thousand globally, and is projected to reach 3.7 thousand in China and 106.7 thousand globally. With additional efficacy and safety data, BS001 may expand into earlier-line and broader melanoma settings. Now in Phase III development, BS001 has the potential to address significant unmet need and provide a novel therapeutic option for patients with limited alternatives.

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Glioma is a primary brain tumor arising from glial cells, ranging from low-grade forms to highly aggressive GBM. Globally, incidence increased from approximately 293.1 thousand cases in 2020 to 318.9 thousand in 2024 and is projected to reach 360.4 thousand by 2030. In China, incidence rose from 39.5 thousand in 2020 to 45.0 thousand in 2024 and are expected to reach 52.5 thousand by 2030. The global glioma therapeutics market is projected to grow from US\$2.0 billion in 2024 to US\$7.3 billion by 2030, reflecting a CAGR of 24.1%, while China’s glioma therapeutics market is expected to grow from RMB1.9 billion in 2024 to RMB8.3 billion by 2030, representing a CAGR of 27.8%. Conventional therapies are limited by the blood-brain barrier and the immune-privileged nature of the central nervous system, whereas oncolytic viruses can be delivered intratumorally or intrathecally to bypass these barriers and elicit targeted immune responses. Globally, glioma treatment is receiving increasing attention, and in China, fast-track pathways for innovative therapies are accelerating development for rare and high-burden cancers. BS001’s current target population is recurrent or progressive GBM patients who have failed standard-of-care and meet clinical trial criteria. The addressable population in 2024 was approximately 36.5 thousand in China and 258.3 thousand globally, and is projected to reach 42.5 thousand in China and 291.9 thousand globally. With supporting clinical evidence, BS001 may expand into broader GBM settings, including earlier disease stages and combination regimens. As of the Latest Practicable Date, no oncolytic virus therapies had been approved for glioma in China, underscoring significant unmet need and market potential.

CRC incidence increased from 1.9 million cases in 2020 to 2.1 million in 2024 and is projected to reach 2.3 million by 2030 globally. In China, cases rose from 489.8 thousand in 2020 to 542.4 thousand in 2024 and are expected to reach 608.4 thousand by 2030. The global colorectal cancer therapeutics market is expected to reach US\$44.0 billion by 2030, reflecting a CAGR of 9.6% from 2024 to 2030. Over the same period, China’s colorectal cancer therapeutics market is expected to grow from RMB24.2 billion in 2024 to RMB55.5 billion by 2030, representing a CAGR of 14.8%, driven by expanded screening coverage, accelerated drug approvals, increasingly diverse treatment options, more standardized clinical practices and improved healthcare reimbursement. Over 90 percent of metastatic CRC cases are microsatellite stable, characterized by immune-“cold” tumors that respond poorly to checkpoint inhibitors. Current therapies, including chemotherapy and targeted agents, offer limited efficacy, particularly in liver-dominant disease, and immune-based options remain scarce. Oncolytic viruses offer a differentiated mechanism by converting “cold” tumors into “hot” ones through enhanced immune infiltration and antigen presentation, and may be further engineered or combined with PD-1/PD-L1 inhibitors to improve outcomes. Advances in screening and early detection, together with localized delivery approaches such as hepatic artery infusion, further broaden their clinical utility. BS001’s current target population is advanced or metastatic CRC patients requiring subsequent systemic therapy after standard treatment and meeting clinical trial criteria for second-line therapy. The addressable population in 2024 was approximately 414.9 thousand in China and 1.6 million globally, and is projected to reach 465.4 thousand in China and 1.8 million globally. With validation, BS001 may expand into earlier-line settings, combination strategies, and broader molecular subgroups. As of the Latest Practicable Date, no oncolytic virus therapies had been approved for CRC, underscoring substantial unmet need and market opportunity.

Globally, STS incidence rose from 185.3 thousand cases in 2020 to 207.1 thousand in 2024 and is projected to reach 239.1 thousand by 2030. In China, cases increased from 44.5 thousand in 2020 to 50.3 thousand in 2024 and are expected to reach 59.2 thousand by 2030. The global soft tissue sarcoma therapeutics market is projected to reach US\$362.5 million by 2030, reflecting a CAGR of 10.7% from 2024 to 2030. Over the same period, China’s soft tissue sarcoma therapeutics market is expected to grow from RMB204.5 million in 2024 to RMB391.3 million by 2030, representing a CAGR of 11.4%, driven by rising disease awareness, improved diagnostic capabilities and broader access to advanced treatment options. With over 50 subtypes and no established second-line standard of care, soft tissue sarcoma remains highly heterogeneous and often resistant to conventional therapy. Anthracycline regimens offer limited benefit, and checkpoint inhibitors are effective only in select subtypes. Oncolytic viruses provide a subtype-agnostic immune-activation

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approach with potential for both local and systemic effects, alone or in combination with targeted therapies and immune checkpoint inhibitors (ICIs). BS001’s current target population is unresectable or recurrent/metastatic STS patients receiving second-line or later systemic therapy. The addressable population in 2024 was approximately 26.2 thousand in China and 108.1 thousand globally, and is projected to reach 30.9 thousand in China and 124.8 million globally. Given their broad antitumor potential, oncolytic viruses may expand to additional subtypes and earlier-line settings. As of the Latest Practicable Date, no oncolytic virus had been approved for STS, underscoring the unmet need and market opportunity.

Globally, BTC incidence increased from 367.9 thousand cases in 2020 to 419.1 thousand in 2024 and is projected to reach 505.0 thousand by 2030. In China, cases rose from 126.0 thousand to 139.8 thousand over the same period and are expected to reach 161.1 thousand by 2030. The global biliary tract cancer therapeutics market is expected to reach US\$8.0 billion by 2030, reflecting a CAGR of 21.4% from 2024 to 2030. Over the same period, China’s biliary tract cancer therapeutics market is expected to grow from RMB4.1 billion in 2024 to RMB13.7 billion by 2030, representing a CAGR of 22.5%. Prognosis remains poor, with limited benefit from chemotherapy, PD-1 inhibitors, or targeted agents, and median overall survival typically under one year. Oncolytic viruses offer an approach by altering the tumor microenvironment, enhancing sensitivity to immunotherapy, and priming responses to chemotherapy or targeted agents. Regional delivery, including hepatic artery infusion and intratumoral injection, further broadens their utility. BS001’s current target population comprises unresectable, advanced, or recurrent/metastatic BTC patients who have progressed after standard therapy and qualify for third-line treatment. The addressable population in 2024 was approximately 20.4 thousand in China and 61.1 thousand globally, and is projected to reach 78.3 thousand in China and 245.4 million globally. With additional clinical evidence, BS001 may extend to broader BTC subsets, earlier-line use, and combination strategies. As of the Latest Practicable Date, no oncolytic virus had been approved for BTC, underscoring substantial unmet need and opportunity. Please refer to the section headed “Industry Overview” in this document for more information.

Competitive Advantages

Viral Backbone Adopting Dual Knockout and hGM-CSF Insertion Strategy with High Druggability Potential

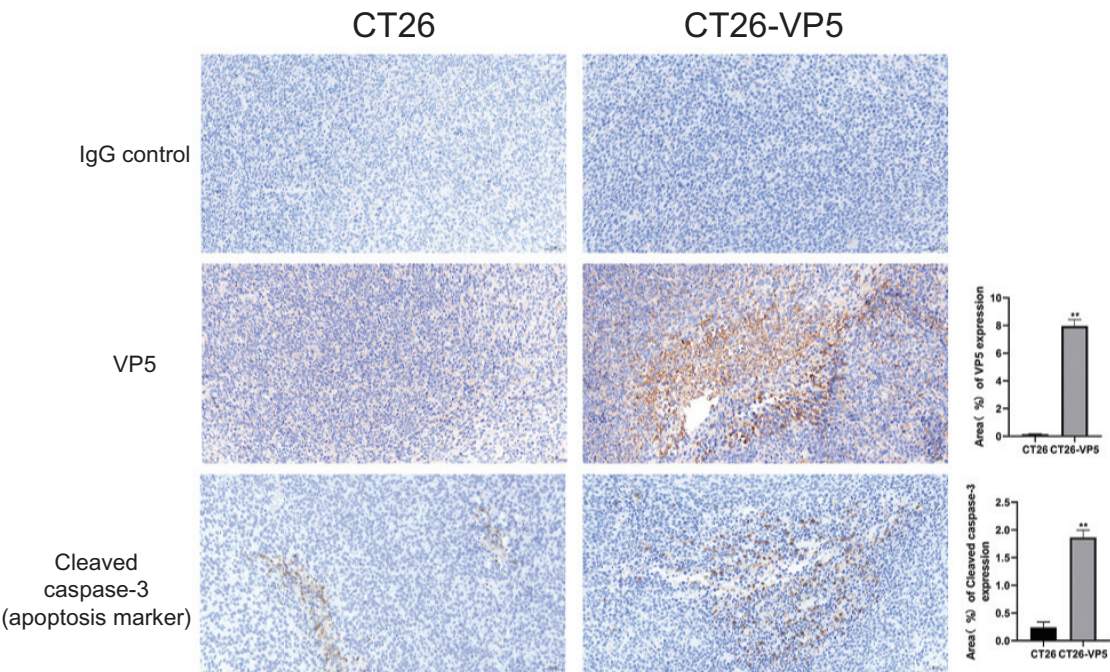
BS001 is built on an HSV-2 backbone, characterized by strong intratumoral replicative capacity, resistance to neutralizing antibodies, and a high exogenous cytokine-carrying capacity. Compared with HSV-1, HSV-2 demonstrates higher intracellular activity and stronger oncolytic potency, further strengthening its therapeutic potential. Specifically, HSV-2 offers the following advantages: (i) higher oncolytic activity; (ii) stronger ability to evade host antiviral immunity, thereby supporting more efficient viral replication upon infection; (iii) enhanced stimulation of NK cell-mediated cytotoxicity against tumor cells; (iv) greater propensity to induce syncytia formation, which promotes antitumor immune responses; and (v) engagement of a broader range of antitumor pathways. Preclinical data support that oHSV-2 exhibits superior antitumor activity. In the CT-26 colorectal tumor model, oncolytic HSV-2 expressing hGM-CSF produced substantially greater tumor growth inhibition than the corresponding oHSV-1 construct, demonstrating that oHSV-2 has stronger oncolytic potency. These features position HSV-2 as a highly suitable viral backbone candidate for the development of oncolytic virus therapies. Clinical trials to date have shown favorable outcomes, underscoring BS001’s potential as a leading product in its field.

The dual knockout of ICP34.5 and ICP47 restricts viral replication to tumor cells and restores antigen presentation, a clinically validated design adopted by all approved HSV-based oncolytic viruses, thereby enhancing safety, efficacy, and differentiation within oncolytic virus therapies. In addition, BS001 incorporates the hGM-CSF and the feasibility and druggability of this modification strategy have also been validated in clinical trials of approved oncolytic viruses.

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Through the above backbone selection and engineering strategies, BS001 has been constructed with intended dual mechanisms of action—direct oncolysis of tumor cells and induction of systemic antitumor immunity. In terms of direct tumor cell killing, BS001 is capable of inducing apoptosis across a variety of tumor cell types. With respect to systemic antitumor immunity, it activates T cells, NK cells, and macrophages, while reversing the immunosuppressive effects of regulatory T cells (Tregs) and MDSCs. As demonstrated by the diagrams below, mechanistic studies confirmed that BS001 induces tumor cell apoptosis and modulates immune checkpoints such as NKG2A, thereby reinforcing its potential to overcome resistance to standard therapies. Tumors expressing viral protein 5 (VP5) (CT26-VP5) exhibit markedly higher VP5 staining and increased cleaved caspase-3 signals compared with control tumors, indicating that the VP5 protein of BS001 triggers apoptosis in tumor cells. These findings provide translational rationale for advancing BS001 into clinical development.

The Structural Protein VP5 of Oncolytic Virus BS001 Induces Apoptosis in Tumor Cells



Source: Company data

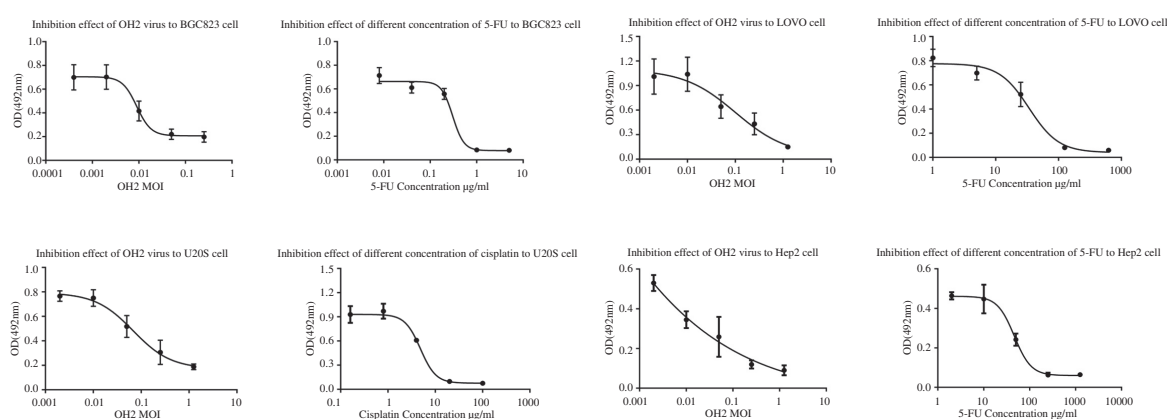
Our design of BS001 has facilitated its progression into the clinical development. It is poised as the world’s first HSV-2-based oncolytic virus candidate to reach clinical stage and the first of its class to advance into a Phase III pivotal trial, underscoring its potential to become the first approved therapy of its class globally. BS001 is in Phase III clinical development for unresectable or metastatic melanoma, positioning it among the most clinically advanced oncolytic virus candidates globally and the most advanced domestically developed oncolytic virus program in China. BS001 has the potential to become the first approved HSV-2 oncolytic virus therapy globally, with support of its demonstrated OS benefits as the primary endpoint. BS001 is among the very few oncolytic virus candidates that adopt OS as the primary endpoint, consistent with draft guidance issued by the FDA.

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Favorable Safety and Efficacy Profile Demonstrated by Comprehensive Preclinical and Clinical Data

Preclinical data demonstrate that, because BS001 incorporates a dual knockout design (ICP34.5 and ICP47) together with hGM-CSF insertion, it achieves enhanced tumor selectivity, and immune activation. In pharmacology studies, both *in vitro* and *in vivo* experiments across multiple solid tumor models demonstrated that BS001 exhibited greater antitumor activity compared with conventional chemotherapy. The following diagrams demonstrate the dose-dependent inhibitory effect of our BS001 as compared to chemical agents (5-FU or Cisplatin) on the four distinct cancer cell lines (BGC823 cell, LOVO cell, U2OS cell, and Hep2 cell). Each panel illustrates the dose-dependent inhibition of cell viability, with BS001 showing progressively stronger cytotoxic effects as multiplicity of infection (MOI) increases, while 5-FU and cisplatin display marked reductions in viability only at higher concentrations beyond their respective threshold doses. These findings demonstrate that BS001 achieves potent antitumor activity across multiple cancer cell lines, comparable to or exceeding that of conventional chemotherapeutic agents, supporting its potential as a differentiated therapeutic modality.

Comparative Antitumor Effects of OH2 Virus, 5-FU, and Cisplatin in Human Cancer Cell Lines



Source: Company data

The Phase Ia/Ib trial of BS001 monotherapy in patients with unresectable or metastatic melanoma demonstrated promising overall survival outcomes. As of August 15, 2025, the one-year survival rate reached 91.0% and the two-year survival rate was 72.0%. Our current mOS has achieved 46.6 months. The longest survival observed in Phase Ia subjects was 76.7 months, significantly superior to historical controls. In this trial, approximately 75% of patients had refractory acral lentiginous melanoma, a subtype that is more aggressive, less responsive to immunotherapy, and associated with poorer prognosis compared with the cutaneous subtype, which is more common in Caucasian populations. The ORR was 34.48%, and notably, among patients with PD-1 inhibitors-resistance disease, the ORR reached 42.1%, also markedly superior to historical benchmarks.

Clinical trials have demonstrated that BS001 exhibits a favorable safety profile across multiple solid tumor indications. As of June 27, 2025, among 421 patients treated with BS001, 75.06% experienced TRAEs, with 10.69% being CTCAE grade ≥ 3 and 4.76% classified as serious adverse reactions. Adverse events leading to treatment discontinuation occurred in 1.43% of patients, and no treatment-related deaths were reported. Overall, BS001 demonstrated a manageable safety profile with no new safety signals observed, showing improved results as compared to the publicly available data of other industry players as of the Latest Practicable Date.

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The following table summarized the safety data observed in the trials:

Adverse event category	Total (N=421), n (%)	Adverse Reaction	Cases	Incidence (% N = 421)
Treatment-related adverse events	316 (75.06%)	Pyrexia	177	42.04%
Grade ≥ 3 adverse reactions	45 (10.69%)	Anemia	39	9.26%
Serious adverse reactions	20 (4.76%)	Increased aspartate aminotransferase	34	8.08%
Adverse reactions leading to study discontinuation	6 (1.43%)	Increased alanine aminotransferase	34	8.08%
Adverse reactions leading to death	0	Nausea	27	6.41%
		Vomiting	27	6.41%
		Increased γ -glutamyl transferase	24	5.70%
		Fatigue	23	5.46%
		Decreased white blood cell count	22	5.23%

Source: Company data

Broad Pipeline Across High-Value Solid Tumor Indications Enabled by Synergistic Modalities, Multiple Administration Routes and Proprietary Manufacturing and Formulation

BS001 has advanced into clinical trials across a variety of indications, including unresectable or metastatic melanoma, unresectable or relapsed/metastatic CRC, relapsed GBM, unresectable or relapsed/metastatic STS, unresectable or relapsed/metastatic BTC, each of which represents a therapeutic area with significant unmet clinical need. By specifically targeting patients with advanced-stage disease where no established standard of care exists, BS001 has the potential to provide alternative treatment options for hard-to-treat indications and to improve patient outcomes upon approval and commercialization. Moreover, BS001’s ability to alter the tumor microenvironment enhances its synergy with established treatment modalities. For example, intratumoral administration upregulates immune checkpoint expression, thereby priming tumors for combination with checkpoint inhibitors. In addition, co-administration with chemotherapy augments immunogenic cell death, promotes antigen release and T-cell activation, and helps mitigate resistance pathways. We are currently evaluating BS001 in combination with PD-1 inhibitors in Phase II trials across multiple solid tumor indications, reflecting the therapeutic potential of BS001.

BS001 supports a variety of administration routes, including intratumoral and intracranial injection, enabling tailored therapeutic approaches for different tumor types. In addition to these core modalities, bladder instillation, intrathoracic and intraperitoneal perfusion, and interventional delivery methods are also under exploration. As part of these exploratory administration approaches, an investigator-initiated clinical trial evaluating intravesical administration of BS001 in patients with bacillus Calmette-Guérin (BCG)-failed non-muscle-invasive bladder cancer is currently being conducted by a tertiary hospital in Wuhan. The trial is designed as a single-arm, multicenter Phase II study to evaluate the safety and preliminary efficacy of intravesical administration of the therapy in approximately 40 patients. The study was initiated in December 2025. For glioblastoma specifically, administration via Ommaya reservoir provides a direct and clinically practical route to target intracranial tumors. Moreover, BS001 features proprietary manufacturing and formulation technology, including a lyophilized product design that facilitates convenient storage and distribution. Current stability studies have shown that the viral titer of BS001 remains stable after nine repeated freeze-thaw cycles, stable for two weeks at 2–8°C, one week at 20–25°C, and up to 24 months under –70°C conditions. These attributes enable a off-the-shelf supply and support broad clinical accessibility, underpinned by a robust CMC framework.

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Summary of Clinical Trial Data

We have initiated clinical trials of BS001 in melanoma, CRC, GBM, STS, and BTC, and we are actively advancing a broad clinical development program for BS001 across a variety of solid tumor types. The following table sets forth an overview of some of the clinical trials of BS001:

Product	CTR Number	NCT Number	Indication	Mono/Combo	Trial Phase	Study Design	Region	Trial start date	(Planned) Trial completion date	Status	Number of Enrolled Participants
BS001	CTR2018222	NCT04386967	Unresectable or metastatic melanoma	Mono	Phase Ia ⁽¹⁾	An open-label, single-arm dose-escalation study to determine the MTD and DLT of intratumoral administration of BS001 in humans, and to evaluate its safety and tolerability.	China	2018/11	2020/04	Phase I evaluation has been conducted.	9
				Mono	Phase Ib ⁽¹⁾	An open-label dose-expansion study to evaluate the antitumor efficacy of BS001.	China	2020/04	2022/02	Phase I evaluation has been conducted	35
	CTR20223472	NCT05868707	Unresectable or metastatic melanoma	Mono	Phase III	A randomized, controlled, open-label study to evaluate the efficacy of BS001 by intratumoral injection in patients with unresectable or metastatic melanoma who have failed at least second-line standard therapy.	China	2023/03	2026 Q4	Enrollment was completed for 230 of 340 patients as of March 27, 2026	230
	CTR20190278 ⁽²⁾	NCT03866525	Unresectable or relapsed/metastatic CRC	Mono/Combo with a PD-1 inhibitor	Phase I	An open-label, dose-escalation study to determine the MTD and DLT of intratumoral administration of BS001, alone or in combination with a PD-1 inhibitor, in humans, and to evaluate its safety and tolerability.	China	Mono: 2019/04 Combo: 2020/06	Mono: 2020/04 Combo ⁽³⁾ : 10 ⁶ dose level completed in 2020/09; 10 ⁷ dose level completed in 2020/10; 10 ⁸ dose level was completed in 2022/09	Completed	5
				Combo with a PD-1 inhibitor	Phase II	An open-label, dose-expansion study to evaluate the antitumor efficacy of intratumoral administration of BS001, alone or in combination regimens, and to further assess its safety.	China	2020/09	2024/01	Completed	26
	CTR20211817	NCT05235074	Relapsed GBM	Mono	Phase I	An open-label, single-arm dose-escalation study to determine the MTD and DLT of intracavity administration of BS001 and to evaluate its safety and tolerability.	China	2021/11	2024/08	Phase I evaluation has been conducted.	17
					Phase II	An open-label, single-arm dose-expansion study to evaluate the preliminary antitumor activity of intracavity administration of BS001, and to further assess its safety.	China	2024/08	2026/06	Phase II enrollment has been completed, and the Phase III protocol is under preparation	23
	CTR20190278 ⁽²⁾	NCT03866525	Unresectable or relapsed/metastatic STS	Mono/Combo with a PD-1 inhibitor	Phase I	An open-label, dose-escalation study to determine the MTD and DLT of intratumoral administration of BS001, alone or in combination with a PD-1 inhibitor, in humans, and to evaluate its safety and tolerability.	China	Mono: 2019/04 Combo: 2020/06	Mono: 2020/04 Combo ⁽³⁾ : 10 ⁶ dose level completed in 2020/09; 10 ⁷ dose level completed in 2020/10; 10 ⁸ dose level was completed in 2022/09	Completed	3
				Combo with a PD-1 inhibitor	Phase II	An open-label, dose-expansion study to evaluate the antitumor efficacy of intratumoral administration of BS001, alone or in combination regimens, and to further assess its safety.	China	2020/09	2024/01	A portion of Phase II evaluation has been conducted.	16
	CTR20190278 ⁽²⁾	NCT03866525	Unresectable or relapsed/metastatic BTC	Mono/Combo with a PD-1 inhibitor	Phase I	An open-label, dose-escalation study to determine the MTD and DLT of intratumoral administration of BS001, alone or in combination with a PD-1 inhibitor, in humans, and to evaluate its safety and tolerability.	China	Mono: 2019/04 Combo: 2020/06	Mono: 2020/04 Combo ⁽³⁾ : 10 ⁶ dose level completed in 2020/09; 10 ⁷ dose level completed in 2020/10; 10 ⁸ dose level was completed in 2022/09	Phase I evaluation has been conducted.	—
				Combo with a PD-1 inhibitor	Phase II	An open-label, dose-expansion study to evaluate the antitumor efficacy of intratumoral administration of BS001, alone or in combination regimens, and to further assess its safety.	China	2020/09	2024/01	A portion of Phase II evaluation has been conducted.	4

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Notes:

- 1 Our Phase Ia/Ib trial of BS001 monotherapy in patients with melanoma in China consisted of two standalone studies, i.e., the Phase Ia dose escalation study and the Phase Ib cohort expansion study. The primary objectives of the Phase Ia study is to determine the MTD and DLT of intratumoral administration of BS001 in humans, and to evaluate its safety and tolerability; while the primary objectives of the Phase Ib study is to evaluate the antitumor efficacy of BS001. From the clinical objective and design perspective, the Phase Ia study for BS001 in melanoma is functionally equivalent to a Phase I clinical trial, and the Phase Ib study for BS001 in melanoma is functionally equivalent to a Phase II clinical trial. As provided in the guidelines issued by the NMPA, the key objectives of a Phase I clinical trial are to (i) assess the new drug's PK and tolerability, (ii) evaluate the DLT and MTD, and (iii) determine the RP2D. The key objectives of a Phase II clinical trial are to (i) assess the antitumor activity, and (ii) provide additional data on adverse events and toxicity. These key objectives are substantially consistent with the respective primary objectives of the Phase Ia and Ib studies for BS001. The primary objectives are also consistent with the ICH guidelines, which the NMPA has affirmed as the reference standard for drug developers in the design and conduct of clinical trials for oncology drugs in its Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》). Accordingly, upon completion of the Phase Ia/Ib studies, the trial results satisfied the primary objectives of the corresponding clinical trial phases consistent with traditional Phase I and Phase II clinical trials. Based on these data, we held an EOP2 meeting with the CDE in June 2022, during which the CDE agreed that we could proceed with a Phase III clinical trial of BS001 in melanoma. The CDE's approval thereby validated our clinical trial design and the corresponding clinical data as meeting the requirements for commencing a Phase III clinical trial. As of the date of this document, we have not received any objections from the CDE regarding the commencement of the Phase Ib study or the subsequent Phase III study in melanoma.
- 2 Unresectable or relapsed/metastatic CRC, STS and BTC are being evaluated under a basket trial design registered under the same CTR/NCT number. Our Phase I/II trial in unresectable or relapsed/metastatic CRC, STS and BTC was initially conducted under the IND approval obtained in June 2018 for BS001 monotherapy in multiple solid tumors, with first dosing of BS001 monotherapy for melanoma in this trial completed in April 2019. In April 2020, during the course of this basket trial, the Company obtained an additional IND approval for BS001 in combination with a PD-1 inhibitor (pucotenlimab as set forth in the clinical protocol) for the treatment of advanced solid tumors and, in June 2020, expanded the basket trial to include this combination regimen across multiple solid tumor indications, including unresectable or relapsed/metastatic CRC, STS and BTC, with first dosing of the combination completed thereafter. As a result, the finalized design of the basket trial comprises both BS001 monotherapy and BS001 in combination with pucotenlimab across Phase I and Phase II clinical trials. For the three indications of unresectable or relapsed/metastatic CRC, STS and BTC, although both monotherapy and combination cohorts are included, the basket trial is primarily focused on the combination regimen, and all clinical data disclosed in the Document for these indications are derived exclusively from the BS001 plus pucotenlimab combination cohorts.
- 3 The Phase I dose-escalation stage for the combination therapy comprised multiple dose level cohorts, and under the trial design, once dose escalation for a particular dose level was completed, Phase II cohort expansion at that dose level could commence without waiting for the formal completion of the entire Phase I trial. As a result, different dose level cohorts transitioned to Phase II expansion at different times, and the overall completion date of the Phase I trial was later than such transition dates, primarily because patients in 10⁸ dose-escalation cohort remained on study and continued to receive treatment and follow-up due to ongoing clinical benefit. Specifically, under the clinical trial protocol, once the last subject in a given dose cohort had received the first dose and completed the required 21-day DLT observation period, and provided that the safety and tolerability profile was acceptable, dose escalation at that dose level could be considered complete and the study could proceed to Phase II dose expansion without waiting for formal completion of the entire Phase I trial. The Phase I dose-escalation stage for the combination therapy evaluated three dose levels, namely 10⁶, 10⁷ and 10⁸, while the dose of the PD-1 inhibitor in the combination regimen remained constant throughout the trial. Consistent with the protocol, dose escalation for the 10⁶ and 10⁷ dose level cohorts was completed on September 2, 2020 and October 30, 2020, respectively, following which Phase II dose expansion was initiated on September 7, 2020 and December 30, 2020, respectively, while dose escalation for the 10⁸ dose level cohort was completed on September 22, 2022 and did not proceed to Phase II expansion based on clinical evaluation.
- 4 For unresectable or relapsed/metastatic CRC, STS, and BTC, the first patient dosing has been initiated in July 2020, January 2021 and March 2021 for combination therapies, respectively. In addition to the aforementioned indications in the table such as unresectable or metastatic melanoma, unresectable or relapsed/metastatic CRC, relapsed GBM, unresectable or relapsed/metastatic STS and unresectable or relapsed/metastatic BTC, we are actively advancing a broad clinical development program for BS001 across multiple solid tumor types.
- 5 The IND approvals for both the Phase Ia/Ib trial in melanoma and the Phase I/II trials in unresectable or relapsed/metastatic CRC, GBM, and STS were granted as umbrella approvals covering the respective indications. These umbrella approvals comprise (i) the IND approval from the NMPA for BS001 monotherapy received in June 2018, and (ii) the IND approval from the NMPA for BS001 in combination with a PD-1 inhibitor for advanced solid tumors received in April 2020. In accordance with relevant PRC laws and regulations, communication with the CDE is only required before initiating any Phase III clinical trial for each indication. No additional CDE interactions are required for earlier phase trials. Each phase within the combined Phase Ia/Ib or Phase I/II trials constitutes a standalone trial with distinct primary objectives. For BS001, prior to initiating the Phase III trial in melanoma, the Company held an EOP2 meeting with the CDE in June 2022, thereby fulfilling the requirement to consult with the CDE before commencing pivotal or registration studies.

Upon completion of the Phase Ia/Ib studies of BS001 in melanoma, the trial results satisfied the primary objectives of the corresponding clinical trial phases consistent with traditional Phase I and Phase II clinical trials. Based on these data, we held an EOP2 meeting with the CDE in June 2022, during which the CDE agreed that we could proceed with a Phase III clinical trial of BS001 in melanoma. The CDE's approval thereby validated the our clinical trial design and the corresponding clinical data as meeting the requirements for commencing a Phase III clinical trial. As of the date of this document, we have not received any objections from the CDE regarding the commencement of the Phase Ib study or the subsequent Phase III study in melanoma.

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Melanoma

Completed Phase Ia/Ib trial of BS001 monotherapy in patients with unresectable or metastatic melanoma in China

We commenced the Phase Ia/Ib trial of BS001 monotherapy in patients with unresectable or metastatic melanoma in November 2018 in China. It is the first-in-human trial for BS001 to evaluate the safety, tolerability, biodistribution, biological activity and efficacy of BS001 following intratumoral injection in patients.

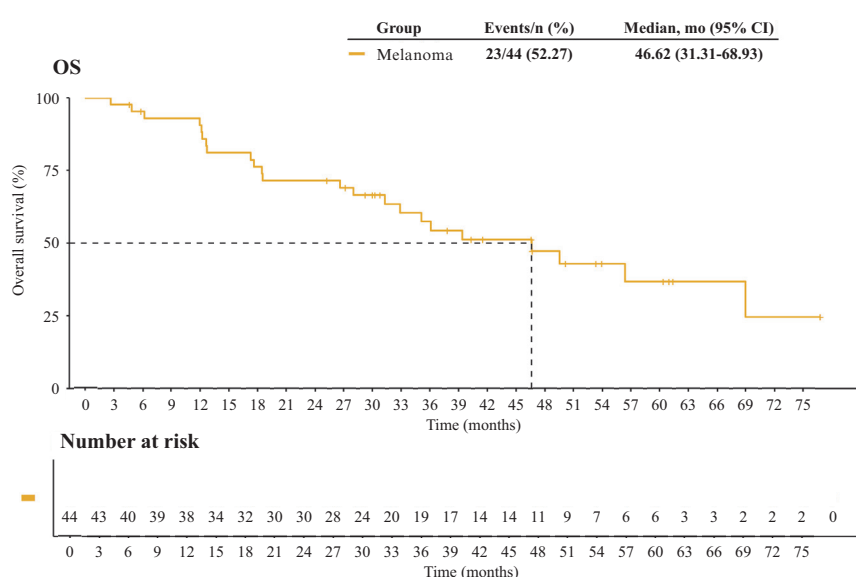
Trial design. This trial is an open-label, single-arm, dose-escalation and dose-expansion study. The primary objectives of the Phase Ia study is to determine the maximum tolerated dose (MTD) and dose-limiting toxicities (DLTs) of intratumoral administration of BS001 in humans, and to evaluate its safety and tolerability; while the primary objectives of the Phase Ib study is to evaluate the antitumor efficacy of BS001. The dose-escalation phase follows the traditional 3 + 3 design.

Trial status. The two portions of this trial have both been completed, with a total of 44 patients enrolled. The Phase Ia study was completed in April 2020, and the Phase Ib study was completed in February 2022.

Safety results. Data from the Phase Ia/Ib trial showed that treatment related adverse events were observed in 68.2% of patients (30 of 44). No grade ≥ 3 adverse reaction, no serious adverse reaction, no discontinuations due to adverse reaction, and no treatment related deaths were observed, indicating a favorable safety and tolerability profile.

Efficacy results. Data from the Phase Ia/Ib trial demonstrated promising overall survival outcomes. The one-year survival rate reached 91.0% and the two-year survival rate was 72.0%. Our current mOS has reached 46.6 months. The longest survival observed in Phase Ia subjects was 76.7 months, significantly superior to historical controls. In this trial, approximately 75% of patients had refractory acral lentiginous melanoma, a subtype that is more aggressive, less responsive to immunotherapy, and associated with poorer prognosis compared with the cutaneous subtype which is more common in Caucasian populations. The ORR was 34.48%, and notably, among patients with PD-1 inhibitors-resistance disease, the ORR reached 42.1%, also markedly superior to historical benchmarks.

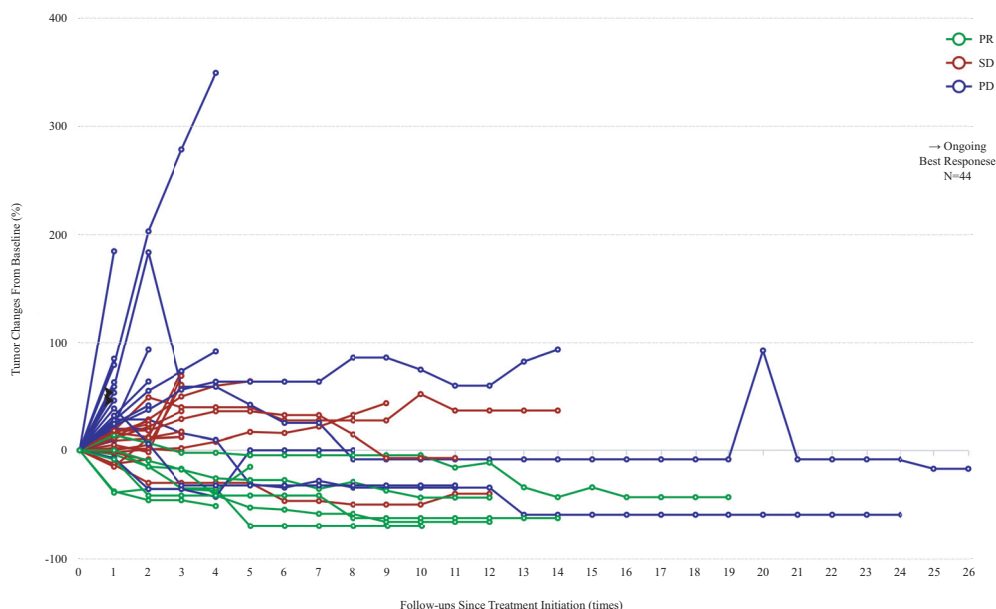
Overall Survival in Melanoma Patients



Source: Company data

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Tumor Response Over Time



Source: Company data

Conclusion. The clinical data from the Phase Ia/Ib trial of BS001 has demonstrated promising safety and efficacy profile, and supports continued development for the treatment of advanced solid tumors. Notably, BS001 is the first and only China-originated oncolytic virus candidate to have secured the ODD from the FDA in melanoma. BS001 was also granted FTD from the FDA in treating unresectable stage III or IV melanoma resistant to or progressed after anti-PD-1 therapy.

Ongoing Phase III trial of BS001 monotherapy for unresectable or metastatic melanoma in China

We commenced the Phase III trial of BS001 monotherapy in patients with unresectable or metastatic melanoma in March 2023 in China. In China, the Phase III clinical trial of BS001 for unresectable or metastatic melanoma has entered the enrollment stage.

Trial design. This Phase III trial is a randomized, controlled, open-label trial evaluating the efficacy and safety of BS001 monotherapy administered via intratumoral injection in patients with unresectable or metastatic melanoma who have failed at least second-line standard therapy. The trial includes a treatment group and a control group. In the treatment group, patients are scheduled to receive treatment at a dose of 10^7 CCID₅₀/mL, administered once every two weeks, with a recommended minimum treatment duration of six months. In the control group, patients receive the investigator's choice of therapy or best supportive care. Patients are randomized in a 1:1 ratio to receive either BS001 monotherapy or the investigator's choice of therapy or best supportive care.

The primary objective of this study is to evaluate the efficacy of BS001 compared with investigator's choice of therapy or best supportive care in patients with unresectable or metastatic melanoma who have failed at least two prior lines of standard therapy, including prior PD-1 inhibitors therapy and systemic chemotherapy. The secondary objectives are to evaluate the safety of BS001 under the same conditions and to assess the immunogenicity of BS001 in patients with melanoma. The primary endpoint of the study is OS, which the FDA guidance recognizes as the most clinically meaningful endpoint in oncology drug development. The secondary endpoints include progression-free survival, objective response rate, disease control rate, duration of response, 6-month durable response rate, safety, and immunogenicity as measured by anti-HSV-2 antibody seroconversion.

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Trial status. As of March 5, 2026, a total of 230 patients had been enrolled. The interim data readouts for this trial are expected in the third quarter of 2026.

Completed Phase I/II Trial of BS001 in combination with pucotenlimab in patients with solid tumors, including unresectable or relapsed/metastatic CRC, STS, and BTC, in China

We initiated the monotherapy portion of a Phase I/II basket trial of BS001 in patients with solid tumors, including unresectable or relapsed/metastatic CRC, STS, and BTC, in April 2019, and the combination therapy portion of this trial in June 2020. The basket trial was completed in January 2024, and the program subsequently advanced to Phase II studies targeting specific indications.

Trial design. The Phase I/II trials are single-arm, open-label studies. The primary objectives of the Phase I study is to determine the MTD and DLT of intratumoral administration of BS001 in humans, and to evaluate its safety and tolerability; while the primary objectives of the Phase II study is to evaluate the antitumor efficacy of BS001 in solid tumors.

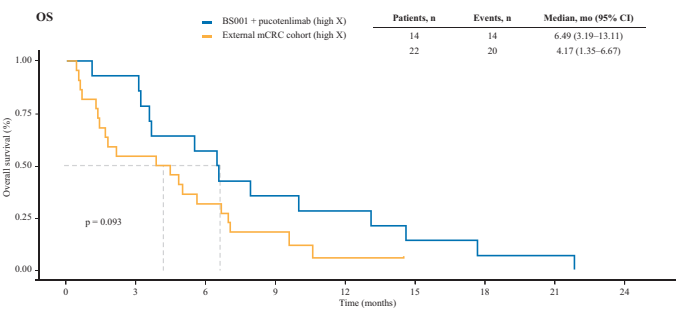
Trial status. The Phase I portion of the basket trial was conducted in two stages. The study in monotherapy cohorts was conducted from April 2019 to April 2020, followed by the combination cohorts evaluating BS001 with a PD-1 inhibitor, which commenced in June 2020, with dose escalation at the 10^6 , 10^7 and 10^8 dose levels completed in September 2020, October 2020 and September 2022, respectively. Across the combination cohorts, BS001 with a PD-1 inhibitor demonstrated more promising efficacy signals compared to monotherapy. Based on these findings, we advanced exclusively into combination regimens for the Phase II portion, which was conducted from September 2020 to January 2024.

Safety results. For unresectable or relapsed/metastatic CRC, data from the Phase II clinical trial completed in January 2024 demonstrated that treatment related adverse events were reported in 58.1% of patients (18 of 31), with grade ≥ 3 events in 16.1% (5 of 31) and serious adverse events in 6.5% (2 of 31). No adverse events led to treatment discontinuation and no treatment related deaths were observed. For unresectable or relapsed/metastatic STS, data from the Phase II clinical trial showed that treatment related adverse events occurred in 89.5% of patients (17 of 19). Grade ≥ 3 adverse events were observed in 10.5% of patients (2 of 19), and serious adverse events in 5.3% (1 of 19). No adverse events led to treatment discontinuation, and no treatment related deaths were reported. For unresectable or relapsed/metastatic BTC, data from the Phase II clinical trial showed that treatment related adverse events occurred in all patients (100%, 4 of 4). One patient (25%) experienced a grade ≥ 3 adverse event, while no serious adverse events, treatment discontinuations, or treatment related deaths were observed. These results suggest that the combination therapy was generally well-tolerated.

Efficacy results. The data from the Phase II clinical trial demonstrated that in patients with unresectable or relapsed/metastatic CRC who had failed standard therapies (primarily third-line or later, with 71% presenting with liver metastases), the longest OS observed in the BS001 plus pucotenlimab group reached 40.1 months, markedly superior to historical controls. Among patients with high expression of biomarker X, the combination of BS001 and pucotenlimab achieved a mOS of 6.5 months, compared with approximately 3–4 months in external controls for the same indication.

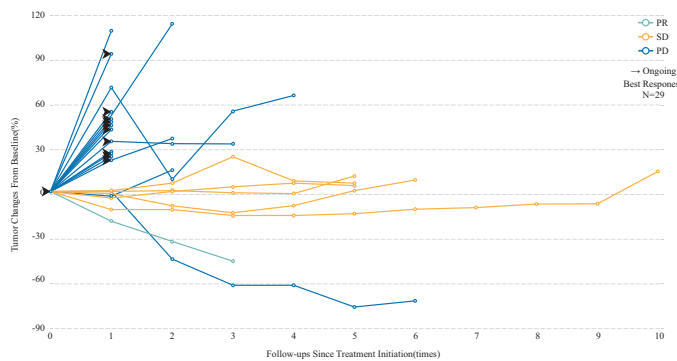
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Improved Survival in Biomarker X High Patients (CRC)



Source: Company data

Best Response Evaluation in Treated Patients (CRC)

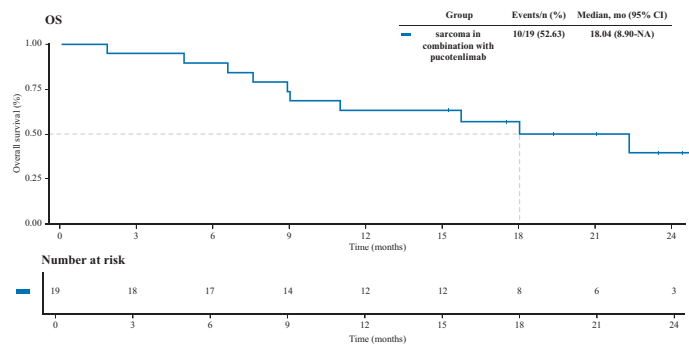


Source: Company data

In addition, for unresectable or relapsed/metastatic STS, data from the Phase II clinical trial completed in January 2024 showed that among 18 patients (44.4% of whom had failed at least three prior lines of therapy), two CRs were observed, with a median overall survival of 18.04 months, again significantly superior to historical controls and the other drug candidate currently most advanced in clinical stage. Moreover, for unresectable or relapsed/metastatic BTC, data showed that, among patients receiving late-line therapy, the longest overall survival reached 33.1 months.

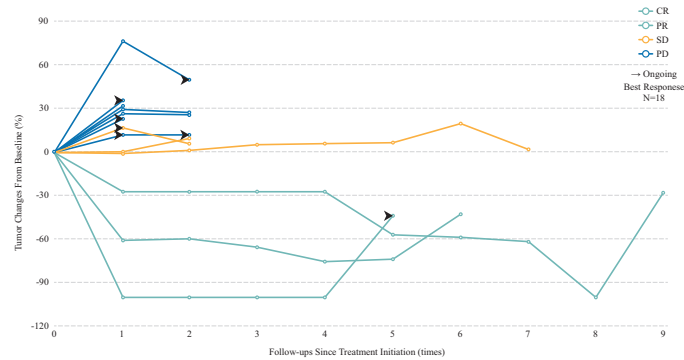
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Overall Survival in STS Patients



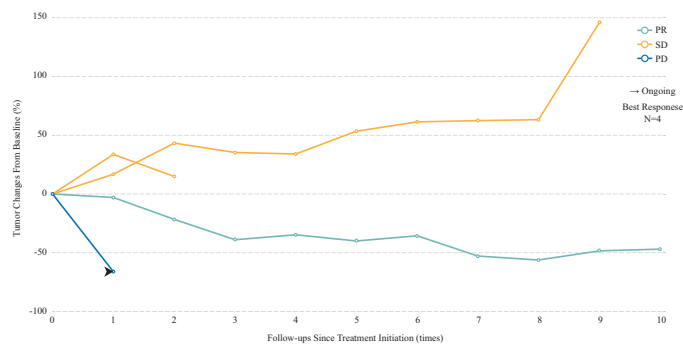
Source: Company data

Best Response Evaluation in Treated Patients (STS)



Source: Company data

Best Response Evaluation in Treated Patients (BTC)



Source: Company data

Conclusion. The clinical data from the Phase II trial of BS001 in combination with pucotenlimab in patients with solid tumors has demonstrated promising safety and efficacy profile, and supports continued development.

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GBM

Completed Phase I/II Trial of BS001 monotherapy in patients with relapsed GBM in China

We commenced the Phase I/II trial of BS001 monotherapy in patients with relapsed GBM in November 2021 in China. Administered conveniently via an Ommaya reservoir, BS001 ensures strong patient adherence, ease of administration, and clear competitive advantages in the treatment of GBM.

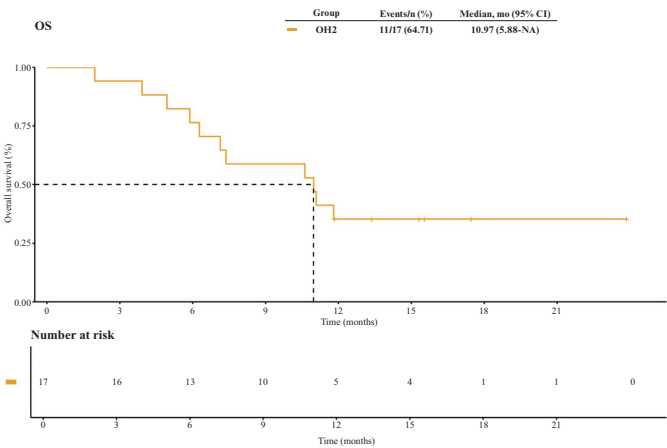
Trial design. This is an open-label, Phase I/II dose-escalation trial designed to evaluate the safety, tolerability, biodistribution, biological activity, and preliminary efficacy of BS001 administered by intracavitary injection in patients with relapsed GBM following surgery. The study follows a 3+3 dose-escalation design in Part 1, with patients receiving either 1×10^6 or 1×10^7 CCID₅₀/mL every three weeks; extended treatment is permitted if no dose-limiting toxicity is observed within 21 days of the first administration. In Part 2, the recommended Phase II dose established in Part 1 will be further evaluated in approximately 22 to 25 patients, who will receive up to six administrations at three-week intervals. Key endpoints include safety, tolerability, preliminary antitumor activity, and biodistribution, assessed through cerebrospinal fluid and blood sampling.

Trial status. A total of 40 patients is enrolled. We completed the Phase I study in September 2024 and completed the enrollment of the Phase II study in June 2025. The Phase III protocol is under preparation and we expect to initiate the Phase III clinical trial in the third quarter of 2026.

Safety results. As of February 10, 2026, TRAEs were reported in 85.0% of patients (34 of 40), including Grade ≥ 3 events in 20.0% of patients (8 of 40) and serious adverse events in 20.0% of patients (8 of 40). Three patients (7.5%) discontinued treatment due to adverse events, and no treatment-related deaths were observed.

Efficacy results. As of September 10, 2024, among the evaluable patients in the Phase I study, the mOS reached 11 months and the ORR was 14.3%. According to Frost & Sullivan, its efficacy profile is similar to the other drug candidate currently most advanced in clinical stage.

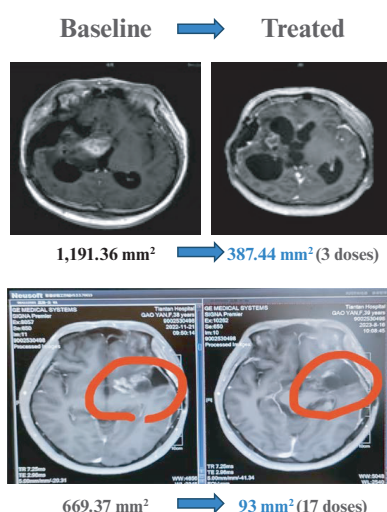
Overall Survival in GBM Patients



Source: Company data

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Tumor Shrinkage in a Patient with PR



Source: Company data

Conclusion. BS001 demonstrated a favorable safety profile and a promising efficacy profile in GBM, supporting its continued clinical development.

Clinical Development Plan

We plan to develop our BS001 both as monotherapy and as a backbone for combination therapy. The table below sets forth details of our further clinical development plan for BS001:

Indication ¹	Mono/Combo	Clinical Trial Stage	Location	(Expected) First Patient Enrollment Date	The Next Milestone
Unresectable or metastatic melanoma	Mono	Phase III	China	March 2023	Expected Q4 2026 submission of BLA
			U.S.	The fourth quarter of 2026	Expected Q4 2026 initiation of Phase III clinical trial
Unresectable or relapsed/metastatic CRC	Combo with a PD-1 inhibitor	Phase III	China	The second quarter of 2026	Expected Q2 2026 initiation of Phase III clinical trial ³
			U.S.	The fourth quarter of 2026	Expected Q4 2026 initiation of Phase III clinical trial
Relapsed GBM	Mono	Phase I/II	China	November 2021	Expected Q3 2026 initiation of Phase III clinical trial
		Phase II ²	U.S.	The fourth quarter of 2026	Expected Q4 2026 initiation of Phase II clinical trial
Unresectable or relapsed/metastatic STS	Combo with a PD-1 inhibitor	Phase III	China	The second quarter of 2027	Expected Q2 2027 initiation of Phase III clinical trial
		Phase II ²	U.S.	The fourth quarter of 2027	Expected Q4 2027 initiation of Phase II clinical trial

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Indication ¹	Mono/Combo	Clinical Trial Stage	Location	(Expected) First Patient Enrollment Date	The Next Milestone
Unresectable or relapsed/ metastatic BTC	Combo with a PD-1 inhibitor	Phase III	China	The fourth quarter of 2027	Expected Q4 2027 initiation of Phase III clinical trial
		Phase II	China	The third quarter of 2026	Expected Q2 2027 completion of Phase II clinical trial
		Phase II ²	U.S.	The second quarter of 2028	Expected Q2 2028 initiation of Phase II clinical trial

Notes:

- 1 The selection of indications reflects the Company’s strategic decisions rather than any of the FDA or NMPA’s recommendations, which are grounded in a comprehensive assessment of multiple factors, including (i) the intrinsic characteristics and therapeutic potential of the drug candidate, (ii) preclinical findings and early clinical data across different disease settings, (iii) the prospective commercial opportunity, and (iv) the competitive landscape associated with each target indication. Moreover, the indications mentioned here are being developed under the same drug registration certificate framework for BS001 and, if approved, are expected to be granted under the same drug certificate. In addition, the clinical adoption of oncolytic virus therapies may be subject to practical constraints. As live biological products, oncolytic viruses may require specialised handling, storage and institutional procedures, which could increase operational barriers to adoption, particularly during the early stages of market development. As clinical evidence, treatment guidelines and reimbursement mechanisms continue to mature, the Company believes that the use of oncolytic virus therapies is expected to expand over time.
- 2 The plan to directly proceed to the Phase II clinical trials in the U.S. is subject to the FDA’s approval. We plan to leverage our established early-stage trial data to proceed directly to a Phase II trial in the U.S. According to Frost & Sullivan, it is common practice in the industry, and permitted by the FDA, to advance to the next phase of clinical trials in the U.S. (such as Phase II or Phase III) based on clinical trial data generated in China. We reasonably believe this anticipated pathway is feasible and understands that the existing clinical data have generated sufficient safety data and preliminary efficacy data to support the commencement of a Phase II clinical trial in the U.S. regulated by the FDA. In addition, we have prior successful experience in obtaining FDA clearance to proceed directly to a Phase III clinical trial in the U.S. based on promising CRC clinical data generated from completed trials in China. We intend to leverage this successful experience in pursuing U.S. clinical trial applications for these indications.
- 3 The Phase II portion was completed in January 2024. To prioritize the path to market in melanoma, we were focusing our resources on advancing the Phase III pivotal trial of BS001 in melanoma. In parallel, we have been conducting a comprehensive retrospective analysis of the CRC data generated from the Phase I/II trial, maintaining ongoing discussion with principal investigators, and further characterizing the novel biomarker that emerged from this analysis. These efforts are intended to refine patient selection and optimize the trial design to best support the Phase III trial in CRC, which we plan to initiate in the first half of 2026. We believe that, based on the available Phase I/II clinical data, our prior development experience, our understanding of the applicable regulatory framework and regulatory expectations, and prevailing industry practice, BS001 is well positioned to advance into Phase III development, and we intend to engage in further communications with the relevant regulatory authorities regarding the specific trial design and development pathway.

We have implemented an adaptive clinical development strategy and may evaluate and adjust our priorities and funding allocations for different indications or other aspects of our clinical trials for each drug candidate from time to time based on the status and results of ongoing clinical trials.

License, Rights and Obligations

We are developing BS001 in-house and own the global rights to develop and commercialize BS001.

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Material Communications with Competent Authorities

The following table provides a summary of material communications with regulatory authorities regarding BS001:

Milestone/Stage	Timeline
FDA clearance through EOP2 meeting for a Phase III trial of BS001 in combination with a PD-1 inhibitor for unresectable or relapsed/metastatic CRC in the U.S. ¹	September 2025
FTD ² granted by the FDA for BS001 in combination with a PD-1 inhibitor in pMMR/MSS colorectal cancer patients with liver metastases (CRCLM) that have progressed on at least three lines of prior therapy	August 2025
FDA clearance through EOP2 meeting for a Phase III trial of BS001 for unresectable or metastatic melanoma in the U.S. ³	December 2024
ODD ⁴ granted by the FDA for the treatment of malignant glioma	February 2024
FTD ² granted by the FDA in treating unresectable stage III or IV melanoma that is resistant to, or has progressed after, anti-PD-1 therapy	June 2023
BTD ⁵ granted by the CDE	February 2023
ODD ⁴ granted by the FDA for the treatment of stage IIb to IV melanoma.	July 2022
IND approval from the FDA for BS001 for the treatment of advanced solid tumor ⁶	August 2021
IND approval from the NMPA for BS001 in combination with a PD-1 inhibitor for advanced solid tumors in patients who failed standard therapy ⁷	April 2020
IND approval from the NMPA for BS001 monotherapy in solid tumors ⁸	June 2018 ⁽⁹⁾

Notes:

- 1 Building upon the positive safety and efficacy data generated in the Phase I/II trial in CRC, we believed that the accumulated data for CRC were sufficient to support advancement to a confirmatory Phase III clinical trial. We therefore submitted applications for a Phase III trial in patients with CRC to the FDA in 2025. The FDA conducted a comprehensive review of our clinical data, including both efficacy and safety profile of BS001, such as OS, ORR, DLTs, MTD, AEs and SAEs and supporting documentation (including CMC and preclinical data such as chemical composition, manufacturing process, quality control, and pharmacology and toxicology information), and subsequently convened an EOP2 meeting. Upon completion of the discussions, the FDA accepted our submitted data in CRC and granted clearance to proceed with the Phase III trial without imposing any further conditions.
- 2 According to Frost & Sullivan, Fast Track Designation may be granted to a drug that addresses an unmet medical need, either where no approved therapy exists or, if therapies are available, where the drug demonstrates a meaningful advantage such as superior efficacy, improved clinical outcomes, fewer serious adverse effects, reduced clinically significant toxicities, earlier or more accurate diagnosis leading to better outcomes, or the ability to address emerging public-health needs.
- 3 Building upon the positive safety and efficacy data generated in the Phase Ia/Ib trial in unresectable or metastatic melanoma, we believed that the accumulated data for melanoma were sufficient to support advancement to a confirmatory Phase III clinical trial. We therefore submitted applications for a Phase III trial in patients with unresectable or metastatic melanoma to the FDA in 2024. The FDA conducted a comprehensive review of our clinical data, including both efficacy and safety profile of BS001, such as OS, ORR, DLTs, MTD, AEs and SAEs and supporting documentation (including CMC and preclinical data such as chemical composition, manufacturing process, quality control, and pharmacology and toxicology information), and subsequently convened an EOP2 meeting. Upon completion of the discussions, the FDA accepted our submitted data in melanoma and granted clearance to proceed with the Phase III trial without imposing any further conditions.
- 4 According to Frost & Sullivan, a drug may qualify for Orphan Drug Designation if it is intended for the prevention, diagnosis, or treatment of a rare disease or condition that affects fewer than 200,000 individuals in the U.S. In assessing this criterion, the FDA considers the best available epidemiological evidence regarding disease prevalence, including incidence, survival, chronicity, and patterns of recurrence, to determine whether the total number of patients eligible for treatment with the drug is reasonably expected to remain below the statutory 200,000-person threshold. A sponsor must provide a credible and well-supported prevalence analysis demonstrating that the target patient population meets this definition of rarity.

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- 5 According to Frost & Sullivan, to qualify for Breakthrough Therapy designation, a drug must satisfy two key criteria. First, the drug must be intended to treat a serious or life-threatening condition, taking into account factors such as the disease’s morbidity, mortality, irreversible progression, or the substantial impact of the condition on day-to-day functioning. Second, and most critically, preliminary clinical evidence must indicate that the drug may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints. Such improvement may include materially higher rates of clinical response, meaningful enhancements in patient-relevant outcomes, or advantages in survival, functional improvement, or other endpoints that reflect tangible clinical benefit. Only when both criteria are met can the FDA grant Breakthrough Therapy designation and provide the accompanying development support.
- 6 We received IND approval from the FDA for BS001 in August 2021 for the treatment of advanced solid tumor. The FDA approved the IND for “Recombinant Oncolytic Herpes Simplex Virus Type 2 Expressing Human GM-CSF gene (OH2), administered by intratumoral injection,” thereby allowing the Company to conduct the clinical investigation in accordance with the protocol and applicable regulatory requirements.
- 7 We received IND approval from the NMPA for BS001 in combination with a PD-1 inhibitor for advanced solid tumors in patients who failed standard therapy. This IND approval does not stipulate lines of treatment. Under the combination-therapy IND approved by the NMPA, BS001 is authorized to be evaluated together with “a recombinant humanized anti-PD-1 monoclonal antibody injection” for the treatment of patients with unresectable, locally advanced or metastatic solid tumors who had failed standard therapy. The IND approval does not specify the product name of the PD-1 inhibitor. However, under the clinical protocol submitted and implemented for this IND, the PD-1 inhibitor used in all combination-therapy cohorts is pucotenlimab (formerly HX008, a PD-1 inhibitor). Accordingly, all clinical data generated under this combination-therapy IND relate to intratumoral BS001 administered together with intravenous pucotenlimab. The clinical indication for the combination cohorts includes patients with various advanced solid tumors who had progressed following or were unable to tolerate standard treatment, representing a second-line or later setting. In the Phase I portion, the primary objectives are to determine the MTD and DLTs of BS001 when combined with a PD-1 inhibitor, and to evaluate the overall safety and tolerability of the regimen. Secondary objectives include preliminary assessment of antitumor activity. In the Phase II expansion stage, the primary objective is to evaluate antitumor efficacy, with secondary objectives including the confirmation of safety, assessment of anti-drug antibodies and immunogenicity, and characterization of the pharmacokinetics of HX008 when administered with BS001. Primary efficacy endpoints include ORR and DCR, evaluated under RECIST v1.1 and iRECIST. Secondary endpoints include DOR, PFS, OS, local symptom improvement at injected lesions, and pharmacokinetic and immunogenicity parameters for the PD-1 inhibitor. Safety endpoints include DLTs, final MTD determination, AEs, SAEs, and changes in vital signs, clinical laboratory values, electrocardiograms, and ECOG performance status. Eligibility criteria for the combination cohorts include adults aged 18–75 years with histologically or cytologically confirmed advanced solid tumors, ECOG performance status of 0–1, life expectancy of at least three months, at least one measurable tumor lesion and one lesion suitable for intratumoral BS001 injection (≥ 0.5 cm), and adequate hematologic, hepatic, renal, coagulation, and immunologic function. Major exclusion criteria include uncontrolled systemic diseases, symptomatic or progressing brain metastases, active infection, immune deficiency or uncontrolled viral hepatitis, prior discontinuation of PD-1/PD-L1 inhibitors due to severe immune-related adverse events, active autoimmune disease requiring systemic therapy, recent investigational-drug exposure, hypersensitivity to herpesvirus-based therapeutics or to the PD-1 antibody, pregnancy or lactation, and any condition deemed unsuitable by the investigator.
- 8 We received IND approval from the NMPA for BS001 monotherapy in June 2018. This IND approval does not stipulate lines of treatment. Under the BS001 monotherapy IND, the clinical development protocol covers a Phase I dose-escalation study and a Phase II expansion study for the treatment of patients with advanced solid tumors. The clinical indication is the intratumoral administration for the treatment of advanced malignant solid tumors. Patients enrolled under this IND generally received BS001 as a second-line or later treatment. In Phase I, the primary objectives were to determine the MTD, DLTs, and evaluate the overall safety, tolerability, and intratumoral biological effects of BS001. Secondary objectives included the preliminary assessment of antitumor activity and treatment-related immune responses. In Phase II, the primary objective was to further assess antitumor efficacy, with secondary objectives focusing on confirming the safety profile of intratumoral BS001. Across both phases, the primary efficacy endpoints included ORR and DCR, while secondary endpoints included DOR, PFS, OS, improvement of local tumor-related symptoms, and immunological markers such as GM-CSF-related RNA and protein expression changes in blood and tumor tissue. Safety endpoints included DLTs, the MTD, AEs, SAEs, and changes in laboratory values, vital signs, electrocardiograms, and ECOG performance status. Patient eligibility criteria required subjects to be 18–75 years of age with histologically or cytologically confirmed malignant solid tumors, ECOG performance status of 0–1, life expectancy of at least three months, at least one measurable or evaluable lesion, and at least one lesion suitable for intratumoral injection (≥ 0.5 cm). Patients must have recovered from prior anticancer therapies and met prespecified hematologic, hepatic, renal, and coagulation thresholds. Key exclusion criteria included uncontrolled systemic diseases, symptomatic brain metastases, active infection, immune deficiency or active viral hepatitis, inability to support intratumoral injection, pregnancy or lactation, recent exposure to investigational agents or antiviral therapies, hypersensitivity to herpesvirus products, active autoimmune disease requiring systemic therapy, and any condition deemed unsuitable by the investigator.

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- 9 We were incorporated in 2010, and our substantial R&D activities commenced in 2012. Prior to obtaining IND approval in 2018, we primarily focused on developing our oncolytic virus platform and Core Product BS001, as well as preparing the requisite IND application materials. From 2012 to 2015, we carried out extensive R&D activities related to BS001, including refining the underlying technologies, optimizing the product’s molecular design, enhancing the CMC process (in particular, building and improving a comprehensive manufacturing process and quality management system), establishing viral seed lot systems and cell banks, conducting laboratory-scale and pilot-scale manufacturing runs, and completing comprehensive preclinical evaluations. From 2016 to 2018, we prepared and submitted the IND application materials, compiling technical documentation, manufacturing data and preclinical study results in accordance with applicable regulatory requirements. In 2016, we completed all required preclinical studies for BS001 and formally commenced preparation of the IND application. In June 2018, we obtained IND approval for BS001 as a monotherapy. Notably, our IND application was submitted in 2017, prior to the CDE’s issuance of updated guiding principles, which subsequently accelerated IND approval timelines for later applicants. According to Frost & Sullivan, our development timeline from research initiation to IND approval was consistent with a normal and appropriate timeframe for the industry under the applicable laws and regulatory regime in effect during our application period.

The IND approvals we obtained from the NMPA for BS001 monotherapy and combination therapy are umbrella IND approvals, which cover multiple phases/stages of clinical trials across different indications, including Phase I or Phase Ia dose escalation study and Phase II or Phase Ib dose expansion study. Since initiating the Phase II or Ib dose expansion study, we have not received any material objection from the NMPA on the commencement or progress of this study. Under Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) in China and our IND from the NMPA, we are required to consult the CDE before commencing pivotal or registrational studies, which we had duly fulfilled through an EOP2 meeting in June 2022 before initiating BS001’s Phase III clinical trial for unresectable or metastatic melanoma in China. We had not received any regulatory agency’s concerns or objections to our ongoing and completed trials of BS001 and clinical development plans as of the Latest Practicable Date.

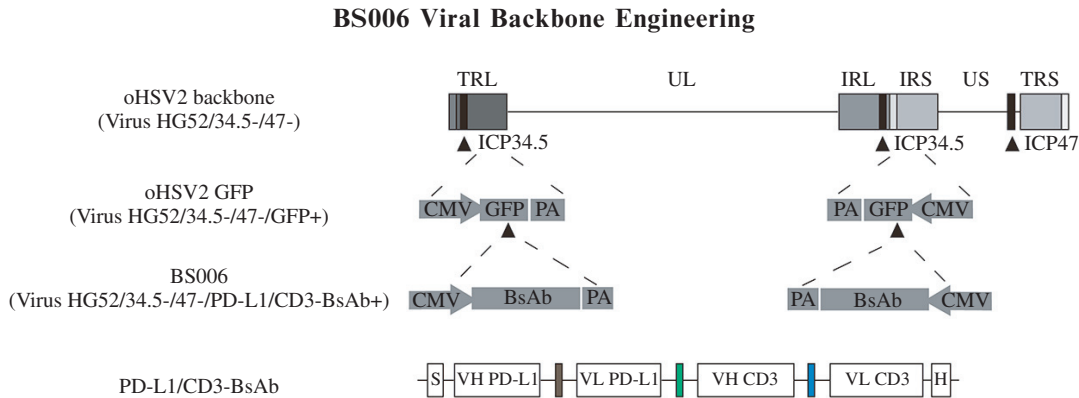
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET BS001 SUCCESSFULLY.

BS006 (oHSV2-PD-L1/CD3-BsAb)—our Key Product

Overview

BS006 is a next-generation oncolytic immunotherapy drug candidate, developed for the treatment of advanced/metastatic solid tumors with high PD-L1 expression, including but not limited to lung, melanoma, liver, pancreatic and colon cancers. BS006 is an HSV-2 engineered by deleting the ICP34.5 and ICP47 and inserting a bispecific antibody targeting CD3 and PD-L1, enabling both direct oncolysis and anti-tumor responses. The figure illustrates the engineering of the BS006 viral backbone derived from the HSV-2 HG52 strain, in which both copies of the neurovirulence ICP34.5 and the immunomodulatory ICP47 are deleted, followed by insertion of exogenous expression cassettes. In the intermediate GFP-tagged construct, a CMV-GFP-PA cassette is introduced at the deleted locus of ICP34.5, which is subsequently replaced in BS006 by CMV-BsAb-PA cassettes to enable the BsAb expression targeting PD-L1 and CD3. The bottom panel details the BsAb structure, including variable heavy (VH) and light (VL) chains for PD-L1 and CD3 binding domains. These modifications enable BS006 to combine oncolytic activity with immune modulation, enhancing tumor targeting and T-cell engagement.

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Source: Company data

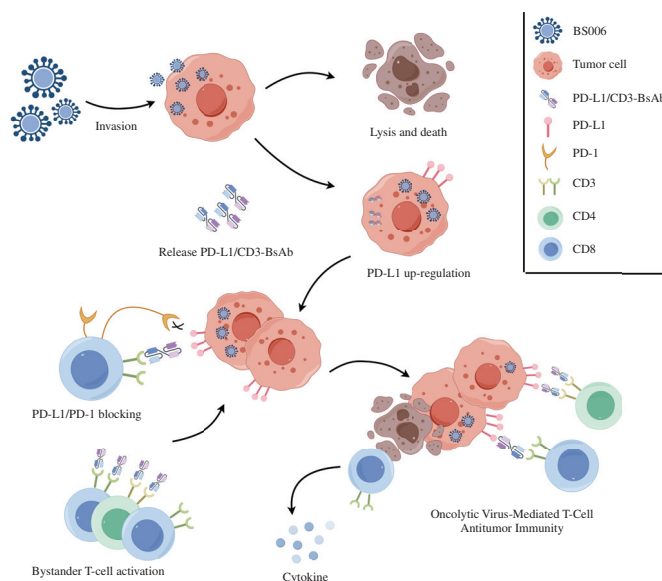
As of January 5, 2026, BS006 Injection had received FDA clearance and entered Phase I clinical development. Five patients with advanced or metastatic solid tumors have been enrolled in the dose-escalation stage. No Grade 3 or TRAEs had been observed. No TRAEs led to early withdrawal, and no treatment emergent adverse events (TEAEs) or TRAEs resulted in death. No suspected unexpected serious adverse reactions (SUSARs) occurred during the study treatment period. One patient with stage IV squamous cell carcinoma has achieved an overall survival exceeding 24.6 months and continues to derive clinical benefit. We expect to initiate the Phase I clinical trial of BS006 for the treatment of solid tumors in China in the second quarter of 2026, complete it in the second quarter of 2027, and initiate the Phase II clinical trial in the third quarter of 2027.

Mechanism of Action

BS006 is an oncolytic virus engineered from an HSV-2 backbone. The dual deletion of ICP34.5 and ICP47 enhances tumor selectivity and safety. In addition, BS006 is armed with a bispecific antibody designed to simultaneously bind PD-L1 on tumor cells and CD3 on T cells, thereby reducing the spatial distance between them and activating T cell-mediated antitumor immune responses. This mechanism enables BS006 to reprogram immunosuppressive cells within the tumor microenvironment, transforming immunologically “cold” tumors into “hot” tumors and promoting robust antitumor immunity. Furthermore, by restricting bispecific antibody expression to the tumor site, BS006 maximizes antitumor efficacy while minimizing systemic toxicity.

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Mechanism of Action of BS006



Source: Company data

Market Opportunity and Competition

BS006 is being developed for advanced and metastatic solid tumors with high PD-L1 expression, including tumors resistant to standard therapies, where unmet need remains substantial. With its differentiated mechanism and potential for combination with T-cell engagers, BS006 may address a broad range of indications and expand across multiple solid tumor segments. The global oncolytic virus market remains early but is growing rapidly. From 2024 to 2030, it is projected to reach USD7.6 billion, reflecting a CAGR of 110.4%. In China, the market grew from RMB23.8 million in 2020 to RMB45.3 million in 2024 (CAGR of 17.4%) and is expected to surge to RMB9.2 billion by 2030, representing a CAGR of 142.5%.

In parallel, the market for T-cell engagers, where BS006 has strong combination potential, is also set for substantial growth. Globally, the market is expected to expand from USD3.2 billion in 2024 to USD40.7 billion in 2030 (CAGR of 52.7%). In China, it is projected to grow from RMB0.7 billion in 2024 to RMB8.3 billion in 2030 (CAGR of 67.4%), according to Frost & Sullivan. As of the Latest Practicable Date, no TCE-expressing oncolytic virus candidates had been approved, and all remained in clinical development, according to Frost & Sullivan.

Competitive Advantages

Expanding Therapeutic Potential with an HSV-2 Backbone, Dual Knockouts, and Bispecific T-Cell Engager Insertion

BS006 is constructed on an HSV-2 backbone that provides superior intracellular activity, stronger oncolytic potency, and greater immune evasion capacity compared with HSV-1. This backbone also supports NK cell activation, syncytia formation, and engagement of diverse anti-tumor pathways, underscoring its suitability for oncolytic virus development. The dual knockout of ICP34.5 and ICP47 confines viral replication to tumor cells and restores antigen presentation, a clinically validated strategy that enhances both safety and efficacy. In addition, BS006 is engineered to express a bispecific antibody that targets PD-L1 on tumor cells and CD3 on T cells, thereby amplifying systemic antitumor immune responses. Despite the commercial success of PD-1 and PD-L1 inhibitors, their response rates as monotherapy remain limited at 10 to 25 percent across most major cancer types, and are particularly low in “cold” tumors that lack T cell

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infiltration. By combining direct tumor cell lysis with immune activation, BS006 has demonstrated the ability to alter the tumor microenvironment, converting “cold” tumors into “hot” tumors that are more responsive to checkpoint blockade. These attributes position BS006 as a potential candidate for combination therapy with PD-1 inhibitors, especially for indications with high need such as lung cancer.

Favorable Safety Profile Demonstrated in Preclinical Studies and Clinical Trials

Our preclinical and clinical data demonstrate a favorable safety profile for our TCE-armed oncolytic viruses, even at higher dose levels. Repeat-dose toxicology studies showed minimal injection-site reactions, limited inflammatory infiltration, and no systemic toxicity, supporting a well-tolerated safety profile. This is because the CD3 sequence of BS006 has been optimized to mitigate the significant toxicity typically associated with non-optimized constructs. Moreover, the local administration of the oncolytic virus ensures that any TCE-related toxicity remains localized, thereby enhancing tolerability. This design is supported by comprehensive preclinical toxicology evaluations, further reinforcing the safety foundation of our programs.

A favorable safety profile has also been observed in clinical trials. In the ongoing Phase I dose-escalation trial as of January 5, 2026, five patients with advanced or metastatic solid tumors have been enrolled. No Grade 3 or TRAEs had been observed. No TRAEs led to early withdrawal, and no TEAEs or TRAEs resulted in death. No SUSARs occurred during the study treatment period.

Enhanced Anti-Tumor Activity through Dual Mechanisms, T Cell Activation, and Bystander Effects

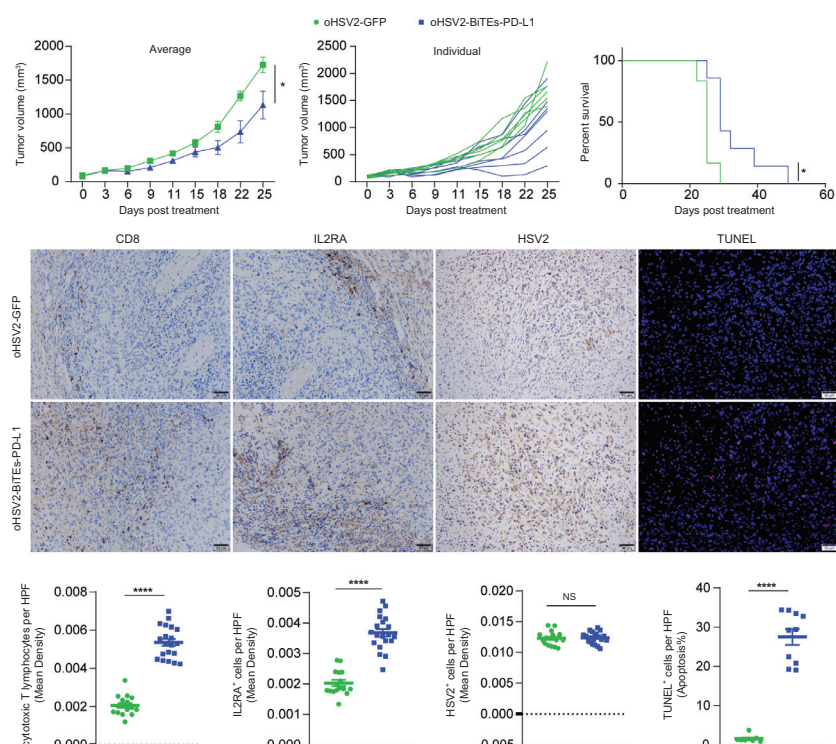
BS006 leverages a triple mechanism of action that integrates direct oncolysis with anti-tumor responses through localized expression of a bispecific antibody. Upon infecting tumor cells, BS006 not only mediates direct tumor cell lysis but also induces the intratumoral expression of a bispecific antibody targeting PD-L1 on tumor cells and CD3 on T cells. This interaction promotes robust T-cell activation and tumor cell killing within the tumor microenvironment, resulting in enhanced local immune responses. Importantly, BS006 extends its anti-tumor effect beyond infected cells by inducing immune-mediated elimination of uninfected PD-L1-positive tumor cells, a phenomenon known as the bystander effect. This feature is particularly valuable in addressing the challenge of tumor heterogeneity, which often limits the efficacy of conventional therapies, and contributes to a broader and more durable therapeutic response.

Furthermore, by combining direct oncolysis with bispecific antibody-driven immune activation, BS006 is designed to maximize anti-tumor activity while minimizing systemic toxicity, as the antibody expression is confined to the tumor microenvironment. In addition, BS006 has the potential to act synergistically with other immunotherapies, such as other immune checkpoint inhibitors and antibody-based therapies, thereby offering opportunities to develop combination regimens that may deliver superior and durable clinical benefit. Collectively, these attributes highlight BS006’s differentiated therapeutic profile and its potential to address significant unmet needs across multiple tumor types.

Preclinical studies of BS006 have demonstrated anti-tumor efficacy profile. In multiple xenograft tumor models, BS006 treatment significantly inhibited tumor growth, improved survival, and induced durable immune-mediated responses, including elimination of uninfected PD-L1-positive tumor cells through a bystander effect. These results provide preclinical validation of BS006’s therapeutic potential across solid tumors and a solid foundation for advancing into clinical development.

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In Vivo Antitumor Efficacy and Immune Activation of BS006



Source: Company data

As of January 5, 2026, data from the ongoing Phase I clinical trial of BS006 further support its favorable efficacy profile. In the dose escalation stage, five patients with advanced or metastatic solid tumors were enrolled. One patient with stage IV squamous cell carcinoma has achieved an overall survival of more than 24.6 months and continues to experience clinical benefit, highlighting the therapeutic potential of BS006 in solid tumors.

Summary of Clinical Trial Data

Ongoing Phase I Trial of BS006 monotherapy in patients with advanced or metastatic solid tumors in U.S.

Trial design. This is a Phase I, open-label clinical trial to evaluate the safety, tolerability, and to determine the maximum tolerated dose (MTD) of BS006 administered via intratumoral injection in subjects with advanced or metastatic solid tumors who have failed all available standard-of-care therapies. The trial employs a standard 3 + 3 dose-escalation design to assess dose-limiting toxicities (DLTs) across sequential cohorts, with the objective of identifying the MTD and/or recommended Phase II dose. Patient will be 18 years and older and histologically confirmed advanced or metastatic solid tumors and must have failed all available standard-of-care therapies or be intolerant/ineligible for such therapies. Dosing frequency is once every two weeks; three dose levels in planned escalation and max total injection volume per visit is 8mL.

Trial status. We launched this trial in December 2023, and expect to complete the trial in the fourth quarter of 2026. As of January 5, 2026, five patients with advanced or metastatic solid tumors have been enrolled and received treatment in the dose-escalation adverse reactions of the clinical trial.

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Safety and efficacy results. As of January 5, 2026, no Grade 3 or TRAEs had been observed. No TRAEs led to early withdrawal, and no TEAEs or TRAEs resulted in death. No SUSARs occurred during the study treatment period. One patient with stage IV squamous cell carcinoma has achieved an overall survival exceeding 24.6 months and continues to derive clinical benefit.

License, Rights and Obligations

We are developing BS006 in-house and own the global rights to develop and commercialize BS006.

Material Communication with Competent Authority

We received the IND approvals from the FDA and NMPA for BS006 in November 2022 and August 2025, respectively. We had not received any regulatory agency’s concerns or objections to our ongoing Phase I trial of BS006 and clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET BS006 SUCCESSFULLY.

Cocktail Approach for Oncolytic Immunotherapy (oHSV2-Cocktail)

We are actively advancing a cocktail approach for multivalent oncolytic immunotherapy, designed as a blend of multiple engineered HSV-2 vectors, each encoding a distinct therapeutic payload. By incorporating diverse payloads, this approach is intended to exert anti-tumor effects through multiple strategies that act on both tumor and immune cells, thereby reducing the risk of drug resistance and enhancing the overall efficacy of oncolytic virus regimens in solid tumors. Our cocktail approach employs a novel strategy that combines multiple HSV-2 vectors, each engineered to express a distinct immunomodulatory or therapeutic nucleic acid sequence, thereby enabling a multifaceted attack on the tumor microenvironment. This approach allows the simultaneous intratumoral delivery of diverse therapeutic payloads, such as immune checkpoint inhibitors, cytokines, or other immune activating agents, designed to stimulate local immune responses while exerting direct antitumor effects. By engaging multiple pathways and targeting both tumor and immune cells, the platform is intended to address tumor heterogeneity, enhance immune cell infiltration, and promote robust and durable antitumor immunity. This mechanism is also expected to convert immunologically “cold” tumors with low immune infiltration into “hot” tumors with high immune activity, thereby overcoming immune suppression in the tumor microenvironment and enhancing therapeutic efficacy. The multivalent design of our cocktail therapy enables the simultaneous targeting of diverse tumor and immune pathways, offering the potential for superior antitumor efficacy compared with traditional monovalent oncolytic virus therapies. In addition, the flexible nature of the platform allows customization of the cocktail composition to address specific tumor types or resistance mechanisms, thereby broadening clinical applicability and enhancing therapeutic durability.

Nucleic Acid Franchise

BR003 (IL-2 analog)—our Key Product

Overview

By harnessing our proprietary nucleic acid RACE[®] platform technology, we have successfully developed our Key Product, BR003, an IL-2 analog encapsulated in LNPs, represents a highly innovative nucleic acid therapy that leverages molecular selectivity and systemic intravenous delivery to achieve efficient transfection and expression. This design induces a potent antitumor immune response while maintaining a compelling safety profile, offering broad therapeutic potential across multiple cancer indications. We expect to initiate the Phase I clinical trial of BR003 for the treatment of solid tumors in the fourth quarter of 2026, complete it in the fourth quarter of 2027, and initiate the Phase II clinical trial in the second quarter of 2028.

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Mechanism of Action

Following administration, BR003 is delivered via a LNP formulation that enters cells and leverages cellular ribosomes to synthesize the IL-2 analog. This engineered IL-2 variant activates antitumor immunity while minimizing the toxicities associated with conventional IL-2 therapy. The resulting expansion and activation of immune effector cells, particularly NK cells and cytotoxic T lymphocytes, promote their infiltration into the tumor microenvironment, where they recognize and eliminate tumor cells.

BR003 leverages our proprietary LNP technology to enable the systemic delivery of therapeutic nucleic acid with enhancing targeting precision and minimizing off target effects by its underlying platform’s engineering. The process begins with the integration of sequence of interest into plasmid vectors, followed by *in vitro* transcription to generate high purity nucleic acid. This nucleic acid is then encapsulated in our proprietary LNPs, which protect it from degradation and ensure efficient delivery after systemic administration. After that, the nucleic acid is translated into therapeutic proteins such as IL-2 analog, which activate cytotoxic T cells and NK cells, thereby promoting anti-tumor immune responses. The IL-2 analog is designed to target the IL-2R $\beta \gamma$ receptor complex, activating the JAK-STAT pathway while avoiding binding to IL-2R α . Compared with conventional IL-2 therapies, this design avoids toxic side effects caused by IL-2R α receptor binding, such as vascular leak syndrome and over-activation of regulatory T cells, while maintaining strong antitumor immune activity.

The platform underlying BR003 can be further engineered to incorporate tumor-specific antibodies, enhancing targeting precision, reducing off-target effects, and enabling more durable immune activation against solid tumors. LNPs also possess inherent adjuvant properties through APC activation. Leveraging this, BR003 integrates a novel IL-2 analog with efficient LNP delivery to achieve potent, selective immune stimulation while maintaining a significantly improved safety profile versus wild-type IL-2. This dual innovation addresses long-standing limitations of IL-2-based therapies and provides a strong translational rationale for systemic treatment of advanced solid tumors. Supported by robust pharmacology, toxicology, and mechanistic data, BR003 is well positioned to advance into early-phase clinical trials. If validated clinically, it has the potential to become a breakthrough immunotherapy with both monotherapy and combination applications.

Market Opportunity and Competition

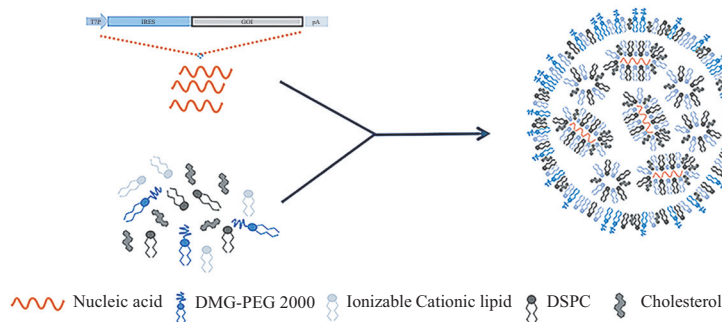
Liver and lung cancers, two of the most common and lethal malignancies, illustrate the scale of unmet need, as existing therapies often fail to deliver durable benefit. IL-2 plays a well-established immunostimulatory role by binding to the IL-2 receptor complex (CD25, CD122, CD132), promoting T-cell proliferation, enhancing NK-cell activity, and strengthening antitumor immunity. Although approved IL-2 drugs such as Proleukin® and Xinluoer® have shown clinical efficacy, their use is limited by severe toxicities, including capillary leak syndrome, and a narrow, dose-dependent therapeutic window. BR003 is designed to overcome these constraints.

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Competitive Advantages

Unique “capless” nucleic acid structure and Receptor-Selective IL-2 Analog Platform

Mechanism of “Capless” Encapsulation Technology



Source: Company data

Our proprietary platform integrates a unique “capless” nucleic acid structure with a receptor selective IL-2 analog design. The capless structure replaces the conventional 5' cap with an internal ribosome entry site (IRES) element and incorporates UTP in place of chemically modified nucleotides, thereby streamlining the *in vitro* transcription process and quality control while decreasing the cost. Building on this backbone, the engineered IL-2 analog is designed to selectively bind IL-2R $\beta \gamma$ without engaging IL-2R α , preserving potent effector T cell and NK cell activation while minimizing dose limiting toxicities such as vascular leak syndrome and regulatory T cell overactivation, which have historically constrained IL-2 based therapies.

The preclinical studies demonstrated that BR003 activates T cells and NK cells, mediate anti-tumor immune response, and achieves efficacy in multiple tumor-bearing mouse models without inducing systemic toxicity, highlighting its translational potential for treating advanced solid tumors. Moreover, BR003 exhibited pharmacokinetics and biodistribution profiles without significant accumulation, and showed tolerability and safety in repeated-dose and safety pharmacology studies.

Versatile and Modular LNP Delivery System

Our bespoke lipid delivery system, which is fabricated via automated microfluidic mixing, yields 70–120 nm particles with polydispersity indices ≤ 0.3 and encapsulation efficiencies exceeding 90%, protecting nucleic acid from nuclease degradation and enabling rapid, flexible clinical responsiveness. This system also scales efficiently, producing more than 100,000 doses per batch. Moreover, biological tailoring such as integrating antibody conjugation, dual-payload delivery, can further broaden the therapeutic potential, thereby unlocking new opportunities for precision delivery and significant market potential. In addition, it supports systemic intravenous administration, expanding clinical applicability, while its modular design enables rapid substitution of therapeutic nucleic acid payloads to address diverse cancer targets and indications without the need to reinvent the delivery system.

Favorable Safety Profile

Extensive GLP-compliant toxicology studies demonstrated good overall tolerability, with no evidence of severe systemic toxicities or central nervous system or respiratory effects, and confirmed a wide safety margin against hemolysis. In a pivotal GLP study, Sprague Dawley (SD) rats received intravenous administrations of IL-2 analog-LNP at high, medium, and low doses once weekly for six weeks (a total of seven doses), followed by a four-week recovery period. All animals tolerated the

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treatment well and survived until study completion. Under these conditions, the No Observed Adverse Effect Level (NOAEL) was identified at the highest tested dose, providing a solid basis for determining the starting dose in subsequent human clinical trials.

Rapid and flexible production

This platform enables rapid generation of candidate drugs and fast, target-specific development based on new targets or tumor-associated antigens. Unlike conventional protein therapeutics that require months to produce, our approach allows short-cycle creation and testing of candidates, reducing development timelines from months to weeks. This agility supports quick iteration, personalized applications, and timely response to emerging therapeutic needs.

Clinical Development Plan

BR003 has demonstrated potent anti-tumor activity and a favorable safety profile in animal models. We submitted an IND to the FDA in March 2026 for advanced solid tumors. We expect to submit an IND to the NMPA in the third quarter of 2026.

BS051

BS051 was developed using LNPs to achieve systemic delivery of oncolytic viruses, with the viral nucleic acid encapsulated within the LNPs. This strategy enhances stability, protects the viral nucleic acid from degradation, and facilitates efficient delivery to tumor sites. By overcoming the limitations of intratumoral injection, BS051 has been formulated for intravenous delivery, offering the potential to expand the therapeutic scope of oncolytic virotherapy to advanced solid tumors where local administration is not feasible.

Upon administration, the LNPs deliver viral nucleic acid into tumor cells, where it undergoes translation and replication, resulting in the generation of infectious viral particles. The process culminates in cell lysis, releasing new viral particles that propagate infection to neighboring tumor cells, amplifying the oncolytic cascade. In addition to direct lysis, BS051 could also induce tumor cell death through activation of intrinsic apoptotic pathways. The destruction of tumor cells releases tumor-associated antigens, along with viral pathogen- and damage-associated molecular patterns, which collectively stimulate both innate and adaptive immune responses. Transmission electron microscopy confirmed the successful recovery of viral particles following BS051 infection of tumor cells.

BS051 demonstrates its competitive advantages through its systemic delivery potential and novel mechanism of action with tumor selectivity. Unlike many oncolytic viruses limited to intratumoral administration, BS051 is formulated for intravenous offering the potential to expand the therapeutic scope of oncolytic virotherapy, thereby extending applicability to non-accessible or metastatic tumors. In addition, BS051 delivers the complete viral nucleic acid via LNPs, enabling efficient viral replication exclusively in susceptible tumor cells. This tumor restricted activity minimizes the risk of off-target toxicity and enhances the therapeutic index compared with conventional LNP-based therapies.

Preclinical studies demonstrate that BS051 exerts potent, tumor selective antitumor activity through viral replication, oncolysis, and apoptosis, achieving robust efficacy across multiple tumor models with evidence of complete responses in certain cases. Notably, BS051 has shown a favorable safety profile, providing strong support for advancement into IND enabling studies. The use of LNPs enables a streamlined manufacturing process with lower contamination risk and more controlled costs. With improved delivery and encapsulation capabilities, the LNP platform can encapsulate both therapeutic payloads and viral nucleic acids, supporting in vivo replication. BS051 leverages this platform for systemic delivery of oncolytic viruses via intravenous administration, allowing efficient transfection and expression and inducing a potent antitumor immune response with a favorable safety profile.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET NUCLEIC ACID PRODUCT CANDIDATES SUCCESSFULLY.

Protein Drug Franchise

Leveraging our Protein Biologics Platform, we are also developing innovative therapeutic protein targeting neurological disorders and other selected indications. This innovative production system enables the efficient, rapid, and safe production of biologically active recombinant protein, overcoming many of the limitations associated with traditional fermentation or mammalian cell expressions systems.

PROPRIETARY TECHNOLOGY PLATFORMS

We were incorporated in 2010, and our substantial R&D activities commenced in 2012. Prior to obtaining IND approval for BS001 in 2018, we primarily focused on developing our oncolytic virus platform and Core Product BS001. The viral vector platform represents our core technology platform and serves as the backbone of our technical capabilities. The primary objective of this platform is to develop oncolytic virus drug candidates. Leveraging this platform, we have successfully developed our Core Product BS001 and Key Product BS006. This platform also enables us to continue developing novel oncolytic virus assets and facilitating the cocktail approach for multivalent oncolytic immunotherapy.

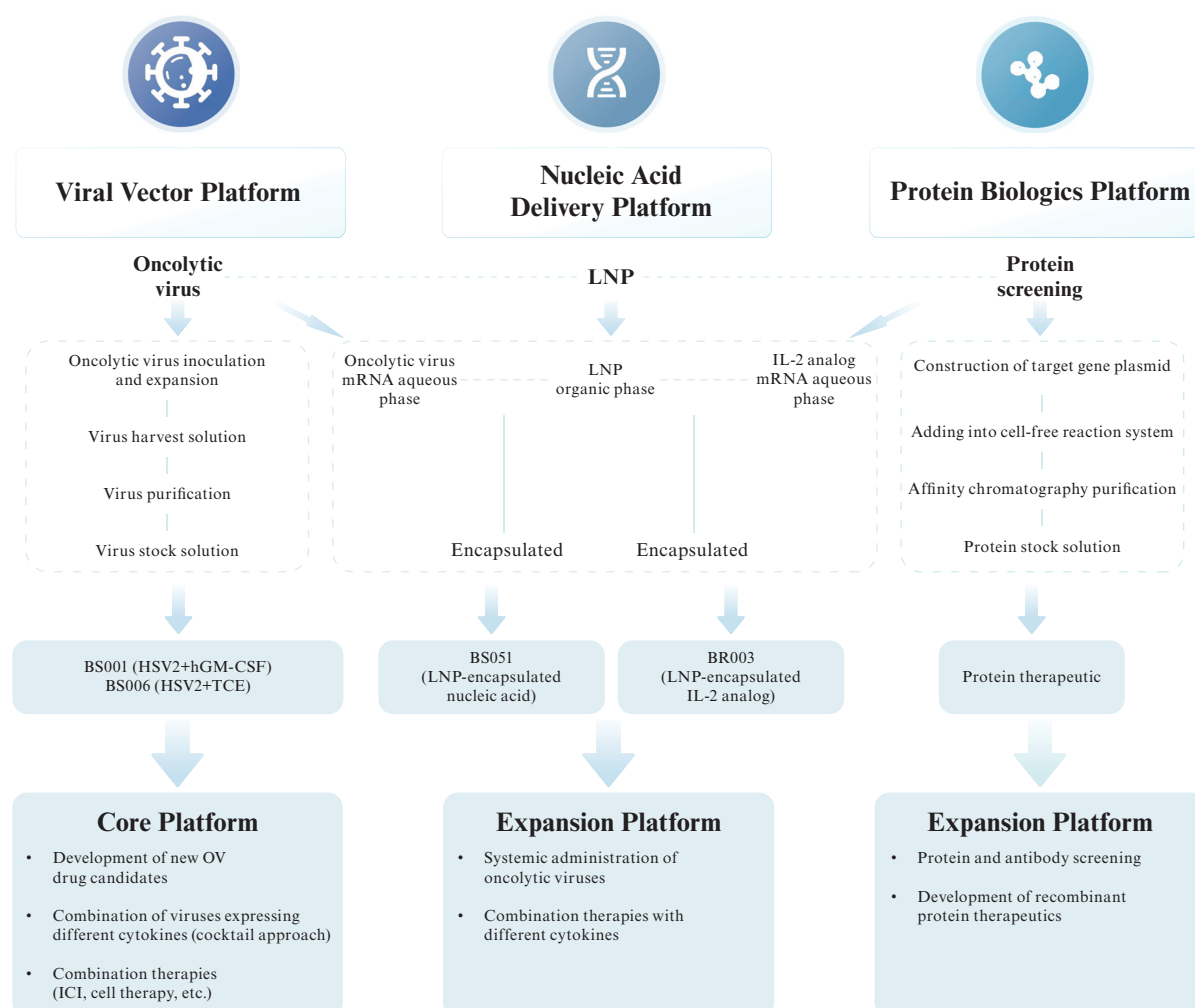
While achieving breakthroughs in drug development through the viral vector platform, we have been progressively accumulating related technical capabilities. In 2019, we successfully established two expanded platforms: the nucleic acid delivery platform and the protein biologics platform. The initial strategic consideration of developing the nucleic acid delivery platform was to address technical challenges in delivery and enable systemic administration of oncolytic virus therapeutics. The initial strategic consideration of developing the protein biologics platform was to facilitate the screening of proteins and antibodies. These two platforms synergize effectively with the viral vector platform, maximizing our technical capabilities and product clinical potential. However, both the nucleic acid delivery platform and the protein biologics platform also possess independent therapeutic development potential. For instance, the nucleic acid delivery platform enables combination therapies with different cytokines, while the protein biologics platform facilitates the development of recombinant protein drug candidates. Through the nucleic acid delivery platform, we have successfully developed BR003, our Key Product, and BS051. Leveraging our protein biologics platform, we are also developing innovative therapeutic protein targeting neurological disorders and other selected indications.

The research and development team for our technology platforms has remained stable and has been consistently led by Dr. Liu Binlei since we substantially commenced R&D activities in 2012. We will continue to advance and leverage these three technology platforms to achieve additional technical breakthroughs and develop pipeline products.

The diagram below outlines the technical pathways and future development trajectories of our respective platforms, which together achieve vertical integration from vector construction under the viral therapeutics platform, to delivery optimization under the nucleic acid therapeutics platform, to functional enhancement under the protein biologics platform, forming a complete R&D continuum. They also realize horizontal synergy, as each platform reinforces the others, with nucleic acid delivery technologies improving the administration of viral and protein therapeutics and the protein platform enhancing the viral therapies.

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Platform Technology Roadmaps and Future Development Trajectories



Source: Company data

Viral Vector Platform. We have established a comprehensive viral vector platform that is primarily focused on HSV-2, while also retaining the capability to develop other oncolytic viruses. Backed by more than 20 years of team experience in fundamental research and platform development, this platform spans the entire lifecycle, from early proof of concept studies, CMC process development and quality management, and clinical trial registration and execution, to commercial scale manufacturing and sales. In addition, the platform supports the development of multiple viral backbones, including HSV-1, adenovirus, and coxsackievirus, enabling versatile applications across oncolytic virotherapy. Our proprietary viral vector platform and deep know-how enable us to explore a cocktail approach for multivalent oncolytic immunotherapy that combines multiple engineered HSV-2 vectors, each encoding a distinct therapeutic sequence. By targeting both tumor and immune cells through diverse mechanisms, this approach reduces the risk of resistance and enhances the efficacy of oncolytic virus therapies in solid tumors.

Nucleic Acid Delivery Platform. Our nucleic acid delivery platform is differentiated, built on proprietary intellectual property and a leading development system. We pioneered the nucleic acid structure that omits the 5' cap and does not rely on modified uridine, offering a simplified process with lower cost and enhanced pharmacological activity. This structure has been applied to the development of nucleic acid based drugs, vaccines, antibodies, and protein replacement therapies. In addition, we have independently developed a series of liposomes as well as proprietary encapsulation

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devices for small and pilot scale production, further strengthening our core technological capabilities and addressing key process bottlenecks. Leveraging this platform, we are innovatively combining oncolytic viruses with nucleic acid therapeutics to develop a new class of oncolytic nucleic acid medicines.

Protein Biologics Platform. The platform integrates innovative expression technologies with next-generation purification systems to ensure high productivity, safety, and scalability. It is built on two core pillars: (i) a prokaryotic cell-free protein expression system that enables the rapid synthesis of structurally complex proteins, and (ii) a trimer-tag rapid purification technology that achieves efficient recovery of high-purity (>97%) proteins. Together, these capabilities not only accelerate internal R&D efficiency but also support the development of the therapeutic proteins for diverse clinical applications. Currently, we are advancing a self-developed recombinant protein therapeutic for neurological disorders that is undergoing preclinical evaluation.

RESEARCH AND DEVELOPMENT

Research and development is a core pillar of our business strategy, underpinning our ability to drive innovation, advance pipeline assets, and maintain a competitive position in the global biotechnology market. We conduct R&D activities primarily through our in-house R&D team. We also engage contract research organizations (“CROs”) from time to time to support our clinical trials and preclinical toxicity studies. In 2024 and 2025, our research and development expenses were RMB102.8 million and RMB84.3 million, respectively. In particular, the research and development expenses incurred for our Core Product were RMB73.9 million and RMB55.5 million during the same years, respectively, accounting for 71.9% and 65.8% of our total research and development expenses for the corresponding years.

Our In-house R&D Team

We place a strong emphasis on academic qualifications, industry experience and complementary expertise when building our R&D team. Our R&D team is spearheaded by Dr. Binlei Liu, our founder and Chairman, who brings over 30 years of research and development experience in tumor immunology and oncolytic viruses. Dr. Liu was a core member of the original R&D team for T-VEC, the first oncolytic virus therapy approved by the FDA, and played an instrumental role in its development. For further details, please refer to the paragraphs headed “Business — Our Competitive Strengths — An Experienced R&D Team and Proprietary Technology Platforms Driving Clinical Progress Across Our Pipeline”.

Our in-house R&D team consists of industry veterans with extensive experience in oncolytic virus research and a proven track record of contributing to the advancement of these innovative modalities. Leveraging this combination of deep industry expertise and multinational best practices, our R&D team underpins efficient and compliant operations across the entire value chain, from research and development to commercial launch. As of the Latest Practicable Date, our R&D team comprised 64 personnel, of whom 28 individuals, representing approximately 44%, held master’s or PhD degrees, primarily in medical science, pharmacology, biology and chemistry. Of these 64 R&D personnel, 63 were involved in the research and development of BS001. Our core R&D team members possess an average industry experience of over 10 years, and bring with them extensive experience at leading multinational pharmaceutical companies and research institutions both in China and abroad. During the Track Record Period and up to the Latest Practicable Date, we did not experience any departures of core R&D personnel, nor were there any material disputes related to core R&D personnel or any material adverse impact on the Company’s business arising from personnel departure matters. None of the R&D employees who departed during this period, if any, owned or retained any material assets, technical know-how or intellectual property relevant to the Company. We also maintain close cooperation with prominent healthcare professionals in our R&D endeavors.

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Four core personnel, including Dr. Liu, are responsible for the discovery and development of BS001. Dr. Liu, our founder, leads the scientific direction of the program, while the other team members, who joined the Company between 2012 and 2021, each have extensive experience in R&D and related functional disciplines, and contribute substantially to the continued advancement of BS001. Mr. Fang Zhizheng joined the Company in January 2012 and has approximately 40 years of experience in the manufacturing and R&D of biological products. Mr. Wang Hanming joined the Company in June 2021 and has extensive experience in the clinical registration and operations. Ms. Xia Nan joined the Company in July 2021 and has built a long-standing career in biological product quality management over more than two decades of continuous practice.

R&D Process

Our R&D activities were primarily conducted in China. Our laboratories are fully compliant with GMP requirements and certified to Biological Safety Level 2 (BSL-2) standards. We have established a comprehensive and systematic R&D project management framework that spans the entire drug development lifecycle. This framework is designed to optimize resource allocation, accelerate development timelines, and enhance the probability of success for our innovative drug candidates.

Our drug discovery process focuses on unmet medical needs, advancing projects after evaluating technical feasibility, market potential, and alignment with our platform capabilities. Leveraging our proprietary technologies and integrated facilities, we conduct process development and pilot studies, establish cell and virus banks, and produce preclinical samples. In the preclinical stage, we perform pharmacology assessments in animal models and outsource comprehensive toxicology and safety studies to accredited GLP institutions, then compile CMC and preclinical data for submission to regulatory authorities in support of IND applications.

Directed by Dr. Liu Binlei, our founder and Chairman, we have placed strong emphasis on building CMC capabilities since our inception. Dr. Liu has led the development of proprietary processes for HSV-2 enveloped viruses, enabling us to address both clinical supply and future commercialization needs while reducing manufacturing costs. We have established an integrated CMC platform covering viral vector construction, cell culture, virus amplification, purification and formulation. Our key strengths include proprietary vector design technologies and our own virus seed bank system reducing reliance on external technologies, efficient clarification, chromatographic purification and ultrafiltration processes tailored for HSV-2 to ensure high viral purity and activity, a comprehensive GMP quality management system adhering to international standards and ICH regulatory requirements, and scale-up capabilities from laboratory to commercial-scale enabling high-yield production with significant cost advantages.

Our clinical development team manages clinical medical affairs, regulatory affairs, pharmacovigilance, and data management to ensure successful development and timely approval of our drug candidates. Throughout clinical trials, we work closely with CROs, trial sites, principal investigators, and regulatory bodies to uphold adherence to study protocols and GCP standards. Our selection of investigators and trial institutions is based on their specialized knowledge, access to suitable patient populations, and operational capacity. We proactively update clinical documentation including the investigator’s brochure and development safety update report to maintain continuous compliance and facilitate successful regulatory reviews.

Collaboration with CROs

In addition to our in-house R&D activities, we also collaborate with reputable CROs to support our preclinical research and clinical trials. Under our oversight such as regular progress meetings, execution reviews, and periodic audits, CROs provide services including site identification, medical and scientific management, data operations and statistical analysis, trial implementation monitoring, regulatory communication, and record keeping and report preparation. We select CROs based on professional qualifications, relevant research experience, service quality, efficiency, industry reputation, and pricing competitiveness. Depending on the specific service requirements, we

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engage CROs through project-based service agreements, which define the scope of work, sample size, procedures, deliverables, timelines, and payment terms. CROs are required to comply with all applicable laws and regulations and adhere to our established protocols, ensuring the accuracy and authenticity of clinical trial results.

Key terms of our CRO agreements typically include the following provisions: (i) CROs shall provide high-quality services including implementation and management of preclinical or clinical research projects as specified in each agreement; (ii) CROs are required to perform services and complete projects within prescribed time limits, usually on a project basis; (iii) we make payments in accordance with agreed payment schedules; (iv) we own all intellectual property rights arising from clinical research projects conducted within the stipulated work scope; (v) CROs are prohibited from disclosing confidential information related to us or our research projects; and (vi) each party indemnifies the other for losses caused by its fault or gross negligence.

COLLABORATION AND MATERIAL AGREEMENTS

In August 2024, we have entered into two collaborative framework agreements with two majority-owned subsidiaries of Lepu Biopharma to jointly evaluate the combination therapy of BS001 and Lepu Biopharma’s pucotenlimab (formerly HX008, a PD-1 inhibitor and LP002 (a PD-L1 inhibitor), respectively, in Mainland China. Lepu Biopharma holds approximately 11.84% and [REDACTED]% equity interest in our total issued Shares as of the Latest Practicable Date and upon the completion of the [REDACTED] (assuming that the [REDACTED] are not exercised), respectively.

Pursuant to the agreements, the parties agree to jointly conduct clinical trials in China for the combination therapy integrating our BS001 and Lepu Biopharma’s pucotenlimab and LP002, respectively. Specifically, Lepu Biopharma will take lead in a Phase I clinical trial of pucotenlimab in combination with BS001 for the treatment of advanced hepatocellular carcinoma and a Phase I clinical trial of LP002 in combination with BS001 for the treatment of advanced solid tumors; whereas we will take lead in a Phase I/II clinical trial of BS001 in combination with pucotenlimab for the treatment of certain advanced solid tumors. Each clinical trial’s protocol, including trial design, dosing regimens, supply schedules, and any amendments thereto, shall be agreed upon by both parties. We are responsible for the supply of BS001, and Lepu Biopharma is responsible for the supply of pucotenlimab or LP002, both subject to the protocol and free of charge. The party leading a given trial assumes all related trial costs including, among others, ethics submission fees, site costs, investigator fees, and third-party contracting costs; whereas the non-leading party bears no financial obligation beyond mutually agreed commitments. Each party must timely share safety information, including adverse events and SAEs arising from the combination use, and must cooperate in risk evaluation and management as required under applicable laws. Each party agrees to use commercially reasonable efforts to provide support for regulatory registration purposes upon request. As of the Latest Practicable Date, the collaboration under the framework agreements is limited to the clinical trials described above in Mainland China. Any further clinical development of the combination therapy, including later-stage clinical trials or clinical trials conducted outside Mainland China, would be subject to further discussion and mutual agreement between the parties in accordance with the terms of the agreements.

As between the parties, each party remains the sole owner of its respective background intellectual property rights. The parties will jointly own all know-how, patents and other intellectual property rights conceived, developed, or reduced to practice by either party (whether solely by or on behalf of such party, or jointly with the other party) during the performance of the agreements.

Unless terminated earlier, the agreements will continue in effect until completion of the clinical trials for the combination therapy and fulfillment of all obligations thereunder. The agreements may be amended or terminated by mutual consent. Any disputes arising out of or relating to the agreements that cannot be resolved through negotiation may be submitted to the competent people’s court at the place of signing.

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The agreements were negotiated and approved on an arm’s length basis and determined based on normal and fair commercial terms considering the therapeutic potential of this combination therapy and potential economic gain for each party.

MANUFACTURING

Established Manufacturing Capabilities

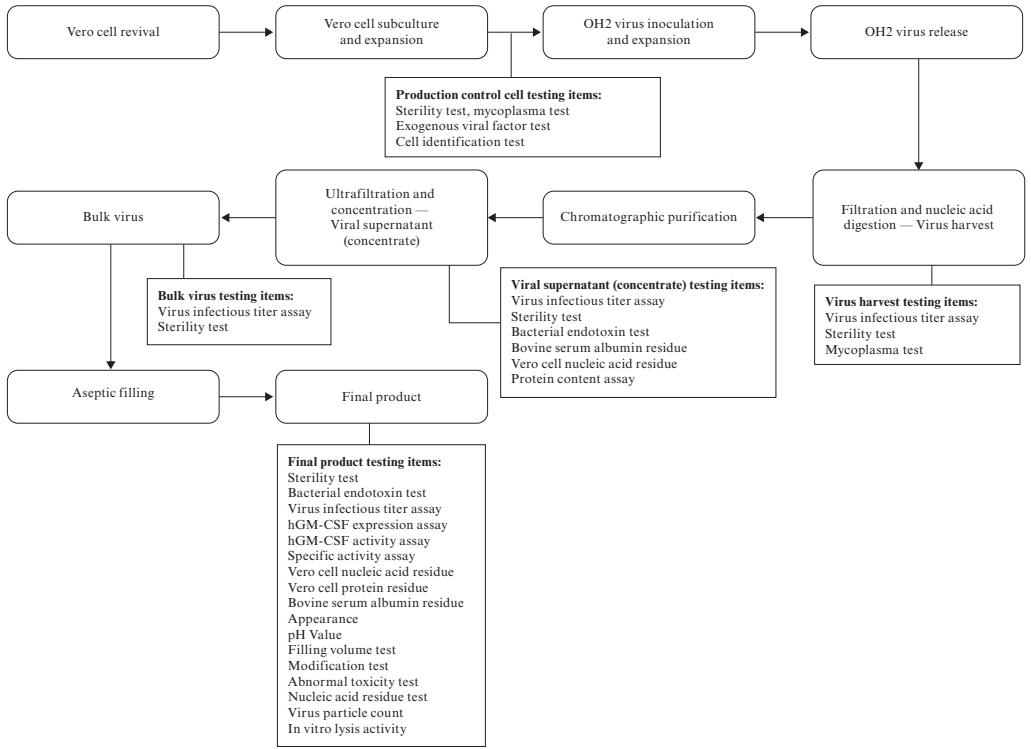
We have established capabilities to manufacture our drug candidates and future drug products. To date, all of our drug candidates were manufactured in-house. We are one of the few companies in China to achieve a full model for the development and production of HSV-2 oncolytic virus candidates. Our manufacturing facilities are equipped with system and equipment from highly reputable manufacturers and suppliers around the world. We conduct regular maintenance and repair work in compliance with applicable GMP requirements. Our quality control system meets rigorous and comprehensive requirements under national and industry standards. We obtained the Drug Manufacturing License (Category A) issued by Hubei Provincial Medical Products Administration. For details, see “Business—Permits, Licenses and Other Approvals.”

We have established GMP-compliant facilities and equipment in Ezhou, Hubei Province to support both the clinical development and future early-stage commercialization of our drug candidates. Our Ezhou base covers a gross floor area of nearly 4,000 sq.m. This production suite is equipped with incubators, biosafety cabinets, bioreactors, chromatography systems and ultrafiltration systems for drug-substance preparation. Pulsating vacuum sterilizers and a washer-dryer linked line are used for sterilizing production tools and primary packaging materials, as well as for decontamination of production waste. The filling-lyophilization line uses isolator technology to maintain aseptic control throughout the dispensing process. Our facilities are equipped with cleanrooms, pharmaceutical-grade water treatment systems, and comprehensive utilities for power, all constructed to the highest standards. Our facilities also have GMP-compliant warehouses for raw materials, intermediates, and finished products. Our principal manufacturing equipment includes cell culture systems, virus production units, purification and ultrafiltration systems, fully automated filling systems, and comprehensive quality control equipment. In addition, we are certified at BSL-2.

Our Ezhou facility achieves a production capacity of nearly 10,000 finished products per batch. Based on current virus titer (7.0 log CCID₅₀/mL, 1 mL/vial), our annual commercial production capacity can reach approximately 700,000 vials, sufficient to support both clinical research and early-stage commercialization, enabling development and production of oncolytic virus drugs. As of December 31, 2025, our manufacturing team comprises 12 members. We strictly comply with regulatory requirements by providing training and examinations for our manufacturing personnel. All team members possess the work experience, knowledge and background that match their positions, and the necessary qualifications that meet the requirements of our manufacturing activities. Employees in specialized roles are further required to obtain the relevant professional certifications. Our manufacturing processes are highly integrated and differentiated, with rigorous quality control implemented at different stages of production. The following diagram summarizes the production and QC process for our oncolytic virus candidates.

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Production and QC Process Flowchart for Recombinant hGM-CSF Oncolytic Type II Herpes Simplex Virus (OH2) Injection (Vero Cells)



Source: Company data

To further expand our manufacturing capacity, we may also construct new GMP-compliant facilities in Wuhan and Shaoxing, China, with the Wuhan facility planned to commence operation in 2027 and the Shaoxing facility in 2028. We believe our current and future manufacturing facilities can provide sufficient supply for our clinical trials and meet the future commercial sales demands of our drug candidates.

QUALITY MANAGEMENT

Quality control and assurance are critical to our continued success. We have established a comprehensive quality management system in accordance with rigorous regulations and guidelines in China and the United States, spanning all key stages from R&D and manufacturing to future commercialization. We closely monitor evolving cGMP standards and regulatory developments, continuously updating our internal procedures to adhere to the highest international standards for patient safety and regulatory compliance. Our dedicated quality management team, including quality control and quality assurance professionals, possesses the requisite work experience and qualifications, with all members required to undergo mandatory pre-job training and examinations. Our quality control and assurance procedures encompass control and inspection of raw materials, management of each step of development procedures, inspection of samples, establishment of product release standards, regular control and inspection of work environment, and risk evaluation during product development.

COMMERCIALIZATION

We currently have no drugs approved or at the commercial stage; however, we have been strategically developing our commercial planning and portfolio management capabilities since our drug candidates entered late stages of clinical trials. For different pipeline candidates, we maintain a targeted and diversified commercialization strategy.

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- **Oncolytic virus candidates.** We will focus on the development and commercialization of our Core Product, BS001, exploring an initial launch in China for lead indications and promoting BS001 on an indication-specific basis as either a monotherapy or in combination therapy, with future expansion centered on the United States as our principal overseas market and, leveraging potential FDA approval, further entry into other major international markets through potential licensing or co-development arrangements. We plan to first explore collaborations with experienced pharmaceutical partners to facilitate market access, sales, and distribution, thereby maximizing market outreach. In the early stage of commercialization, we intend to cooperate with leading pharmaceutical companies in each of our target markets to drive product sales. We may also explore collaborations with contract sales organizations (CSOs) or distributors to cover a broader range of indications. During the first few years of commercialization, we do not plan to establish a full in-house sales team, but will maintain a small internal team to coordinate with our external partners. Depending on market progress and business needs, we may subsequently develop and expand our own dedicated sales team for selected key indications. We intend to implement competitive pricing and market access strategies, including participating in NRDL negotiations, volume-based procurement programs, and leveraging other opportunities to maximize BS001’s market potential and accessibility. In determining the pricing policy, patient affordability, the competitive landscape and the expected cost efficiencies of our products at commercial scale are taken into consideration, alongside market-based pricing references and long-term reimbursement pathways. We will also engage in early market education activities, aiming to establish market awareness and acceptance by physicians, patients, third-party payers and others in the medical community, and explore the inclusion in national reimbursement schemes to improve affordability.
- **Nucleic acid candidates.** We plan to commercialize our nucleic acid candidates as innovative drug products targeting systemic delivery challenges, positioning as next-generation immunotherapy, with differentiated value proposition for hard-to-treat tumors.
- **Protein drug candidates.** We plan to commercialize our protein drug candidates as innovative therapies. We primarily focus on clinical validation at the early-stage, while exploring later-stage potential partnerships for scale-up and market penetration.

Our strategy for entering into collaboration and licensing arrangements is tailored to the specific asset, its stage of development and the competitive landscape in the relevant jurisdiction. For product candidates progressing into later stages of development, we may pursue collaborations with multinational pharmaceutical companies that possess the regulatory expertise and commercial infrastructure necessary to support successful market entry and product launch. For earlier-stage pipeline assets and technology platforms, we are actively evaluating co-development and regional licensing opportunities, particularly with innovative biotechnology companies, which may allow us to retain commercialization rights in key territories such as Greater China. We maintain a flexible approach to transaction structuring, which may include traditional licensing agreements, co-development frameworks or joint ventures, to ensure an optimal strategic and operational fit for each asset.

The identification and selection of collaboration partners is a disciplined process overseen by our executive leadership, with substantive input from our business development and R&D teams. In evaluating potential partners, we prioritize strategic alignment, technical and clinical development capabilities, and a demonstrated commitment to dedicating the resources necessary to advance our product candidates. This rigorous assessment framework is intended to ensure that any partnership we pursue meaningfully accelerates development progress and enhances the overall value proposition of the underlying asset. All prospective arrangements are structured to align with our internal R&D strategy and to safeguard our ownership of core intellectual property rights, particularly in respect of our Core Product.

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We have entered into two collaborative framework agreements with two majority-owned subsidiaries of Lepu Biopharma to jointly evaluate the combination therapy of BS001 and Lepu Biopharma’s pucotenlimab (formerly HX008, a PD-1 inhibitor) and LP002 (a PD-L1 inhibitor), respectively, in Mainland China. For more details, please see “Business—Collaboration and Material Agreements.”

We believe that our differentiated and targeted commercialization strategy has afforded us significant advantages in terms of economic viability and operational efficiency. As we bring our drug candidates into late clinical stage and towards commercialization, we will continue to execute our strategy to ensure an accelerated and smooth market launch for our drug candidates.

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our suppliers primarily included reputable CROs, construction services providers, and providers of raw materials, consumables and equipment, as well as other product and service providers. We have maintained stable business relationships with our major suppliers. 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. For the years ended December 31, 2024 and 2025, our purchases from our five largest suppliers in each period in aggregate accounted for 59.9% and 44.1% of our total purchases for the respective period. Our purchases from our largest supplier in each period accounted for 39.6% and 33.0% of our total purchases for the respective period. The following table summarizes information about our five largest suppliers and our purchases from them during each period of the Track Record Period:

For the year ended December 31, 2025

Supplier	Commencement of business relationship	Background	Major purchases	Payment terms	Purchase amount (RMB in thousands)	Percentage of total purchase
Supplier A	Since 2021	A company primarily engaged in the design and construction of municipal engineering projects.	Engineering Services	14 days	41,777.9	33.0%
Supplier B	Since 2019	A company primarily engaged in providing CRO services.	R&D services	Payment based on milestones	4,821.1	3.8%
Supplier C	Since 2023	A company primarily engaged in the research and development of pharmaceuticals and medical devices, as well as non-clinical safety evaluation.	R&D services	Payment based on milestones	3,773.6	3.0%
Supplier D	Since 2018	A medical public institution.	R&D services	Payment based on milestones	3,166.1	2.5%
Supplier E	Since 2020	A company primarily engaged in technology development in the field of biopharmaceutical science.	R&D services	Payment based on milestones	2,226.8	1.8%
Subtotal					55,765.5	44.1%
Total					126,580.8	100.0%

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For the year ended December 31, 2024

Supplier	Commencement of business relationship	Background	Major purchases	Payment terms	Purchase amount (RMB in thousands)	Percentage of total purchase
Supplier A	Since 2021	A company primarily engaged in the design and construction of municipal engineering projects.	Engineering Services	14 days	52,415.1	39.6%
Supplier D	Since 2018	A medical public institution.	R&D services	Payment based on milestones	9,691.6	7.3%
Supplier B	Since 2019	A company primarily engaged in providing CRO services.	R&D services	Payment based on milestones	9,010.1	6.8%
Supplier F	Since 2023	A company primarily engaged in providing medical research and testing services.	R&D services	Payment based on milestones	4,182.7	3.2%
Supplier E	Since 2020	A company primarily engaged in technology development in the field of biopharmaceutical science.	R&D services	Payment based on milestones	3,912.8	3.0%
Subtotal					<u>79,212.3</u>	<u>59.9%</u>
Total					<u>132,241.9</u>	<u>100.0%</u>

To monitor the quality of supplies, we implement rigorous supplier qualification and selection standards. We have established a comprehensive supplier management policy, and maintain yearly procurement plans. We verify the qualifications, licenses and permits of our suppliers before entering into collaborations, and perform onsite audits on our key suppliers. We also maintain a list of qualified key suppliers, which is subject to regular review and update. To the best of our knowledge, (i) all of our five largest suppliers for each period during the Track Record Period are Independent Third Parties, and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest suppliers for each period during the Track Record Period.

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CUSTOMERS

During the Track Record Period, our revenue was derived from (i) provision of research and development services, (ii) sales of reagents and consumables for R&D purposes, and (iii) other revenue generated from leasing of equipment. For further details, please refer to “Financial Information—Description of Selected Components of the Consolidated Statements of Comprehensive Loss—Revenue.” For the years ended December 31, 2024 and 2025, our revenue from our five largest customers in each period in aggregate accounted for 90.5% and 93.9% of our total revenue for the respective period. Our revenue from our largest customer in each period accounted for 61.2% and 59.8% of our total revenue for the respective period. The following table summarizes information about our five largest customers and our revenue from them during each period of the Track Record Period:

For the year ended December 31, 2025

Customer	Commencement of business relationship	Background	Products/Services purchased	Payment terms	Revenue contribution (RMB in thousands)	Percentage of total revenue
Customer A	Since 2024	A company primarily engaged in biotechnology research and development.	R&D services	Advance payment, balance based on milestones	528.3	59.8%
Customer B	Since 2020	A technology company specializing in providing technical services and research products for life and health sciences.	R&D services	30 days	94.9	10.7%
Customer C	Since 2025	A public institution engaged in medical research.	R&D services	Advance payment	91.5	10.4%
Customer D	Since 2023	A company specializing in R&D services for the applied research of drugs.	R&D services	Partial advance payment with balance due upon acceptance	71.1	8.0%
Customer E	Since 2022	A company primarily engaged in providing outsourced laboratory services.	R&D services and equipment leasing	30 days	43.7	4.9%
Subtotal					829.6	93.9%
Total					883.9	100.0%

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For the year ended December 31, 2024

Customer	Commencement of business relationship	Background	Products/Services purchased	Payment terms	Revenue contribution (RMB in thousands)	Percentage of total revenue
Customer A	Since 2024	A company primarily engaged in biotechnology research and development.	R&D services	Advance payment, balance based on milestones	1,056.6	61.2%
Customer D	Since 2023	A company specializing in R&D services for the applied research of drugs.	R&D services	Partial advance payment with balance due upon acceptance	379.2	22.0%
Customer B	Since 2020	A technology company specializing in providing technical services and research products for life and health sciences.	R&D services and equipment leasing	30 days	63.5	3.7%
Customer F	Since 2024	A public institution in the healthcare sector.	Consumables	Advance payment	33.0	1.9%
Customer G	Since 2024	A company primarily engaged in the research, development, and sales of chemicals.	R&D services	Partial advance payment with balance due upon acceptance	28.3	1.6%
Subtotal					<u>1,560.6</u>	<u>90.5%</u>
Total					<u>1,725.1</u>	<u>100.0%</u>

Notes:

- (1) Customer B was also one of our suppliers during the Track Record Period. We primarily procured R&D services and consumables from Customer B. The purchase amount attributable to such transactions were RMB55.6 thousand and RMB15.4 thousand in 2024 and 2025, respectively, accounting for 0.04% and 0.01% of our total purchases for the same periods, respectively.
- (2) Customer C was also one of our suppliers during the Track Record Period. We primarily procured consumables from Customer C. The purchase amount attributable to such transactions were nil and RMB22.2 thousand in 2024 and 2025, respectively, accounting for nil and 0.02% of our total purchases for the same periods, respectively.
- (3) Negotiations of the terms of our sales to and purchases from Customer B and Customer C were conducted on an individual basis, and the sales and purchases were neither inter-connected nor inter-conditioned with each other. Our Directors confirm that all of our sales to and purchases from these customers were conducted in the ordinary course of business under normal commercial terms and on arm’s length basis. According to Frost & Sullivan, such practice is not uncommon in China’s broad healthcare service industry. Our Directors further confirm that, saved as disclosed above, none of our major suppliers was our customers, or vice versa, during the Track Record Period.

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To the best of our knowledge, (i) all of our customers for each period during the Track Record Period are Independent Third Parties, and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our customers for each period during the Track Record Period.

COMPETITION

The market for oncolytic viruses is evolving and highly competitive. While we are confident that our research and development capabilities allow us to establish a favorable position in the industry, we face competition from both international and domestic biopharmaceutical companies, as well as specialty pharmaceutical and biotechnology firms of varying sizes, along with academic and research institutions. For more detailed insights into the competitive landscape of our drug candidates, please refer to the sections headed “Industry Overview” and “— Our Pipeline.” We believe that the primary competitive factors in our markets include efficacy and safety of drug candidates, manufacturing efficiency, and commercialization development. We anticipate that competition will intensify in the future as additional players enter these segments. Any drug candidate successfully developed and commercialized by us will compete with existing products or any new products that may emerge in the future. For insights into the potential impact of market competition, please see “Risk Factors—Risks Relating to the Research and Development of our drug candidates—We operate in a highly competitive industry, and competitors may discover, develop, or commercialize products more quickly or successfully than we do, which could adversely affect our ability to bring our drug candidates to market.”

INTELLECTUAL PROPERTY

Intellectual property rights are crucial to our business success. We rely on a combination of patent and other intellectual property rights, as well as confidentiality procedures, non-disclosure agreements, employee non-disclosure and invention assignment agreements, and other contractual restrictions to establish and protect our commercially important technologies, inventions and know-how related to our business.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 15 issued patents in China, (ii) two issued patents in the U.S., (iii) one issued patent in other jurisdictions, and (iv) 11 pending patent applications, including seven in China, four in the U.S. As of the Latest Practicable Date, with respect to our Core Product, BS001 or its use, we owned one issued patent in China, two issued patents in the U.S., three patent applications in China and two patent applications in the U.S. Our Directors believe that, with the support of our IP legal advisor’s view, certain of our granted patents or pending applications in China and the U.S. cover the material aspects (e.g. manufactured product; method of manufacture; indication under development) of our Core Product and/or its associated technologies. The following table sets forth the portfolio of patents and patent applications material to our business operations as of the Latest Practicable Date. Our Company is the patent holder or applicant of all the listed patents or patent applications.

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Related Drug/Technology	Patent Name	Patent/Patent Application	Application Number	Jurisdiction	Inventor ¹	Status	Patent holder/Applicant	Application Date	Date of Grant	Expiration Date ²
BS001	RECOMBINANT TYPE II HERPES SIMPLEX VIRUS VECTOR, ITS PREPARATION METHOD, RECOMBINANT VIRUS, PHARMACEUTICAL COMPOSITION, AND APPLICATIONS	Patent	CN201010116275.3	CN	LIU Binlei	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2010-02-09	2014-01-15	2030-02-09
BS001	METHOD FOR TREATING MELANOMA WITH OHSV2	Patent Application	US18/623168	US	LIU Binlei	Pending	BINHUI BIOPHARMACEUTICAL CO., LTD.	2024-04-01	N/A	—
BS001	METHOD FOR TREATING GLIOMA WITH OHSV2	Patent Application	US18/623179	US	Liu Binlei	Pending	BINHUI BIOPHARMACEUTICAL CO., LTD.	2024-04-01	N/A	—
BS001	VIRUS COMPOSITION	Patent	US18/047285	US	LIU Binlei; CAI Linkang; WANG Runyang; ZHANG Siqi; HU Han	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-10-18	2024-12-03	2041-11-15
BS006	BISPECIFIC SINGLE-CHAIN ANTIBODY, RECOMBINANT ONCOLYTIC VIRUS FOR EXPRESSING SAME AND VIRUS COMPOSITION	Patent	US17/568738	US	Liu Binlei; Cai Linkang; Wang Runyang; Zhang Siqi; Hu Han	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-01-05	2022-11-22	2041-11-15
BS006	BISPECIFIC SINGLE-CHAIN ANTIBODY AND ITS APPLICATION	Patent	CN202011265931.6	CN	LIU Binlei; WANG Runyang	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2020-11-13	2021-09-03	2040-11-13
BS001 and BS006	BISPECIFIC SINGLE-CHAIN ANTIBODY, ANTIBODY-LOADED RECOMBINANT ONCOLYTIC VIRUS AND VIRUS COMBINATION	Patent Application	CN202180076298.2	CN	LIU Binlei; CAI Linkang; ZHANG Siqi; HU Han	Pending	BINHUI BIOPHARMACEUTICAL CO., LTD.	2021-11-15	N/A	—
BR003	RECOMBINANT INTERLEUKIN-2 SIMILAR PROTEIN, ISOLATED NUCLEIC ACID, EXPRESSION VECTOR, MRNA, MRNA-LNP LIPID NANOPARTICLES, PREPARATION METHOD AND APPLICATION	Patent Application	CN202410919443.4	CN	LIU Binlei; Norman Jolicoeur	Pending	BINHUI BIOPHARMACEUTICAL CO., LTD.	2024-07-10	N/A	—
BS051	AN IONIZABLE LIPID COMPOUND AND NUCLEIC ACID TRANSFECTION REAGENT FOR IN VITRO USE IN CELLS	Patent	CN202111534575.8	CN	CUI Yanfang; LIU Binlei; Ji Shuaijie; ZHANG Baoqian	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2021-12-15	2022-07-26	2041-12-15
	USE OF AN IONIZABLE LIPID COMPOUND IN NUCLEIC ACID DRUG DELIVERY SYSTEMS	Patent	CN202111534587.0	CN	CUI Yanfang; Ji Shuaijie; ZHANG Baoqian; LIU Binlei	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2021-12-15	2022-08-02	2041-12-15
BS051	A DUAL PROMOTER PLASMID AND ITS CONSTRUCTION METHOD AND APPLICATIONS	Patent	CN202210620366.3	CN	LIU Binlei; CAI Linkang	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-06-02	2023-03-10	2042-06-02
BS051	ENCAPSULATED ONCOLYTIC VIRAL HEREDITARY MATERIAL AND ITS APPLICATION	Patent	CN202210961161.1	CN	LIU Binlei; NI Peng	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-08-11	2023-07-04	2042-08-11

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Related Drug/Technology	Patent Name	Patent/Patent Application	Application Number	Jurisdiction	Inventor ¹	Status	Patent holder/Applicant	Application Date	Date of Grant	Expiration Date ²
BR003 and BS051	AN IONIZABLE LIPID COMPOUND AND ITS LIPID NANOPARTICLES	Patent	CN202310406097.5	CN	LIU Binlei; ZHENG Xiaodi	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2023-04-17	2024-05-28	2043-04-17
BR003 and BS051	A NANO DRUG PARTICLE ENCAPSULATION DEVICE	Patent	CN202323067823.X	CN	LIU Binlei; NI Peng	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2023-11-14	2024-06-18	2033-11-14
Protein Biologics Platform	A MONOCLONAL ANTIBODY TARGETING THE NOVEL CORONAVIRUS SPIKE PROTEIN AND ITS APPLICATION	Patent	CN202210183112.X	CN	LIU Binlei; WANG Runyang; WANG Di	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-02-27	2022-10-21	2042-02-27
Protein Biologics Platform	MONOCLONAL ANTIBODIES TARGETING THE NOVEL CORONAVIRUS SPIKE PROTEIN AND THEIR APPLICATIONS	Patent	CN202211157289.9	CN	LIU Binlei; WANG Runyang; WANG Di	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-02-27	2025-09-09	2042-02-27
Viral Vector Platform	METHOD FOR ACTIVATING IMMUNOCYTES IN VITRO	Patent Application	US17/134209	US	LIU BINLEI; WANG YANG; HU HAN; JIN JING; WANG RUNYANG	Pending	BINHUI BIOPHARMACEUTICAL CO., LTD.	2020-12-25	N/A	—
Viral Vector Platform	METHODS FOR THE INTERACTION OF ONCOLYTIC HERPES SIMPLEX VIRUS VP5 PROTEIN WITH HUMAN LEUKOCYTE ANTIGEN E. AND APPLICATIONS THEREOF	Patent	CN202211149832.0	CN	LIU Binlei; WANG Yang; ZHOU Qin	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-09-21	2023-08-01	2042-09-21
Protein Biologics Platform	HETEROTRIMERIC FUSION PROTEIN, COMPOSITION AND ITS APPLICATION	Patent	CN202211157307.3	CN	LIU Binlei; XU Yan; Norman Jolicoeur	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-09-22	2023-08-01	2042-09-22
Viral Vector Platform	AN ANTI-TUMOR COMPOSITION, A RECOMBINANT PLASMID COMPOSITION AND ITS APPLICATION	Patent	CN202211474029.4	CN	LIU Binlei	Granted	BINHUI BIOPHARMACEUTICAL CO., LTD.	2022-11-23	2023-12-05	2042-11-23

Notes:

- 1 All the inventors of the listed patents or patent applications are our employees or were our employees.
- 2 Patent expiration does not include any applicable patent term extensions.
- 3 We also have three patent applications resulting from third-party collaborations: one with Lepu BioPharma (application number 202510809319.7), one with Beijing Cancer Hospital (application number 202510633072.8), and one with Beijing Tiantan Hospital (application number 202410104366.7). These three patents are presently in the very early stages of substantive examination and have not yet progressed beyond the preliminary review phase, thus are not material to the Company at this stage.

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The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis, depending on factors including the type of patent, scope of coverage, availability of patent term extensions or adjustments, availability of legal remedies, and validity and enforceability. We cannot provide any assurance that patents will issue with respect to our pending or future patent applications, nor that any issued patents will be commercially useful in protecting our drug candidates and methods of manufacturing the same. See “Risk Factors—Risks Relating to Our Intellectual Property Rights” for a description of risks related to our intellectual property.

We enter into collaboration agreements and other relationships with biopharmaceutical companies and other industry participants, through which we may grant access to our own intellectual property, or gain access to the intellectual property of others. See “— Collaboration and Material Agreements.”

We conduct our business under the brand name “Binhui Biopharm” (“濱會生物”). As of the Latest Practicable Date, we had 17 registered trademarks in Mainland China and one registered trademark in Hong Kong. We are also the registered owner of three domain name.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any material claims of infringement, misappropriation or other violations of third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our drug candidates in which we may be a claimant or a respondent. Freedom-to-operate searches and analyses (“**FTO Analysis**”) have been conducted in China and the U.S. in relation to our Core Product. Based on the FTO Analysis, our Directors are of the view that there are no valid and enforceable patents of any third party in these countries that may impact the commercialization of our Core Product in China and the U.S. and we have not infringed any valid and enforceable patents or other IP rights of any third parties.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain identification code, medical data, treatment records and other data of the subjects enrolled in our clinical trials, and such data of the enrolled subjects are desensitized and deidentified. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. We have designed strict data protection policies to ensure that the collection, use, storage, and processing of medical data comply with applicable laws and prevalent industry practices. We also require our CROs to have data protection clauses in our agreements with them, under which they are responsible for safeguarding data in their possession. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Personal information of patients enrolled in our clinical trials and the corresponding clinical trial data are processed solely in accordance with the informed consent form agreed upon by the patients. We have a number of ongoing or planned clinical studies in China and the United States. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China and the United States. We deploy various necessary procedures and management measures to ensure data safety and safeguard the transmission of data provided abroad.

Our Company does not provide products or services directly to individual consumers. During the stage of clinical trials, the main fields of the health and physiological data of the subjects that we process include the subject identification code, gender, age, and the collectable health and

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physiological information of the subjects recorded in the informed consent document (i.e., informed consent form) of the clinical trial after review by the ethics committee. The health and physiological information of the subjects will be uploaded by the researcher to the electronic data capture (“EDC”) system, through which we will obtain relevant data. We will store the data in our self-developed clinical data management system, which has been deployed on our local server and equipped with cybersecurity protection measures (such as firewalls) and login permissions and network access restrictions set for different roles and positions. We hereby make the undertaking that the sole purpose of utilizing the health and physiological information of the subjects that we collected is for the specific clinical trial projects without public disclosure or automated decision-making processes.

We entrust third-party CROs and SMOs to provide professional services and EDC system supplier to provide technological services regarding the process of the health and physiological data of the subjects. We have entered into agreements with the foregoing service providers on information confidentiality, information use, and information deletion. To facilitate the secure handling of subjects’ health and physiological information, we have progressively implemented relevant measures and entered into data protection agreements with our entrusted processors, specifying our right to supervise and verify their processing activities to ensure that they possess security capabilities and technical measures that comply with applicable data protection requirements.

According to Article 80 of the Good Clinical Practice (GCP) for Drug Clinical Trials (《藥物臨床試驗質量管理規範》) (the “**GCP Guideline**”), essential documents for clinical trials used to apply for drug registration should be retained for at least five years after the investigational drug is approved for marketing; for clinical trials not used to apply for drug registration, essential documents should be retained for at least five years after the termination of the clinical trial. Therefore, based on the aforementioned regulatory requirements, when conducting drug clinical trials, we must not delete essential documents and should retain them for at least 5 years after the investigational drug is approved for marketing. According to Article 23 of the GCP Guideline, the researcher is obligated to perform the informed consent of which the latest version of the informed consent form approved by the ethics committee should be used. The researcher should fully inform the subjects of all relevant matters concerning the clinical trial in plain language and expressions that are easy for the subject or their guardian or witness to understand.

The informed consent form includes the research background of the clinical trial, the investigational drug, the health and physiological information collected during the research process, the sponsor’s information, and clearly states that the personal information of the subjects will be anonymized with codes or numbers, and only the researchers will know the subjects’ personal information. Our Company does not have a fixed frequency of updating the informed consent form; it will only be adjusted accordingly based on changes to the clinical trial protocol.

What we can obtain from the EDC system is the identification code and the health and physiological information of the subjects, which cannot be traced back to a specific natural person, nor can the relevant fields.

In order to apply for approval of a U.S. drug clinical trial, we provided the U.S. FDA with over ten pieces of health and physiological information of the subjects, mainly including fields necessary for the application such as gender, age, OH2 injection dosage, and OH2 drug efficacy. The submitted data has been desensitized. For both our Company and the recipient, these fields could not identify a specific natural person, nor could they be used to reconstruct a specific natural person.

Aside from cross-border data transfer associated with our overseas clinical trials, we also conducted cross-border data transfer required for due diligence and [REDACTED] for the Hong Kong [REDACTED] project. As the principal business of our Company does not involve the handling of Important Data, the aforementioned cross-border data transfers did not involve any transfer of Important Data. Our Company has further confirmed that in 2024 and 2025, and for the period from January 1, 2026 up to the Latest Practicable Date, neither our Company nor any of its relevant subsidiaries has, in the aggregate for the respective year/period, transferred overseas (i)

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personal information of more than one million individuals (excluding sensitive personal information), or (ii) sensitive personal information of more than ten thousand individuals. Accordingly, no declaration for a security assessment in respect of cross-border data transfers is required under applicable PRC laws and regulations.

We have designated the General Manager’s Office as the department responsible for managing cybersecurity and data protection matters, and appointed dedicated personnel within such department to serve as the person-in-charge of our cybersecurity and data security, who is specifically responsible for implementing and supervising the management of cybersecurity, data security, and personal information protection. We have progressively formulated and implemented a series of data security management policies and operational procedures, including but not limited to the Data Security Management Measures, Data Classification and Grading Management Policy, Data Security Incident Emergency Response Policy, Data Security Education and Training Plan, Employee Personal Information Protection Policy, Subject Privacy Protection SOP, Supplier Management SOP, Clinical Department Training and Assessment SOP, Clinical Trial Inspection SOP, Clinical Trial Project Documentation Management SOP, and Research Center Closure SOP, among others. The intelligent office systems, finance and supply-chain system used by our Company based on SaaS services have obtained the classification (Level 3) and completed the filing for information system security level protection. The EDC systems related to drug clinical trials used by our Company based on SaaS services have obtained the classification (Level 3) and completed the filing for information system security level protection. The clinical data management system independently developed by our Company has issued a self-classification report on information system security level.

To ensure privacy protection and prevent data leakage, we have implemented classified management of the data it processes; established firewall systems to segregate the network system where servers are located from the office network used by personnel; and installed monitoring systems and visitor logs in critical physical areas and key facilities such as server rooms. The systems are also equipped with automatic virus database updates and log monitoring functions to prevent potential internal and external intrusion risks. The Company has deployed dedicated backup software to perform regular backups of system data deployed locally and implemented corresponding security policies, including point-to-point login and automatic backup. The Company has also established access control measures by assigning different login permissions and network access restrictions to personnel based on their respective roles and responsibilities, ensuring that users access and operate each system according to their designated privileges. Both the SaaS-based systems and the locally deployed clinical data management system used by the Company are equipped with logging, query, and management functionalities for system access and operation records. To ensure the effective implementation of these measures, we have organized training sessions for relevant employees to enhance awareness of data compliance management. According to our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we have, in material aspects, complied with PRC laws and regulations related to cybersecurity, data security and personal information protection. As confirmed by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we are not involved in any litigation, public censure, regulatory investigation or administrative penalties relating to cybersecurity, data security or personal information protection. In view of the ongoing development of PRC legislation in these areas, we will closely monitor regulatory developments and maintain continuous compliance efforts.

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EMPLOYEES

As of December 31, 2025, we had a total of 98 full-time employees, all of which were based in China. The following table sets forth the number of our employees by function as of December 31, 2025:

Function	Number	Percentage
R&D	66	67.3%
Drug discovery and clinical development	38	38.8%
Manufacturing	12	12.2%
Quality Management	16	16.3%
General and Administrative	32	32.7%
Total	98	100.0%

Relationship with Employees

We typically recruit employees through campus recruitment and lateral moves, considering factors including our needs and business plans as well as the candidates’ work experience and educational background. We are dedicated to expanding our talent pool to support future development, ensuring that the departure of any single key management or R&D staff member will not materially or adversely affect our operations. In compliance with the PRC labor law, we enter into standard labor and confidentiality agreements with our employees, covering matters including salaries, employee benefits, confidentiality, intellectual property ownership, non-compete obligations and grounds for termination. We own all the intellectual property rights derived during the course of the work of our employees.

We strive to create an equitable, inclusive, and diverse workplace while fostering positive working relationships with our employees. As of the Latest Practicable Date, we have not established a labor union. All labor disputes are handled in accordance with all applicable laws, rules and regulations. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any strikes or labor disputes that may have a material adverse effect on our business, financial condition or results of operations.

Training and Development

We provide our employees with a diverse array of professional development opportunities and foster a performance-driven environment. With our emphasis on our integrated in-house research and development capabilities, we place significant importance on the growth of internal talent. We consistently seek out advancement opportunities for our staff through various internal and external training and development programs. Our focus is on cultivating a culture that promotes retention and engagement.

Employee Benefits

We are committed to making sure that working conditions throughout our business network are safe and that employees are treated with care and respect. We believe in providing our employees with competitive compensation packages, reflecting our stakeholder-centric ethos, which we believe fosters sustainable and enduring growth. In accordance with PRC regulations, we participate in various government-mandated employee benefit plans, including social insurance such as pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. Our compensation package also comprises paid annual leave, annual physical examination and holiday benefits. During the Track Record Period, we made adequate contributions to these social insurance and housing funds for all employees.

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During the Track Record Period, we did not make full contributions to the social insurance and housing provident funds for certain employees in accordance with the relevant PRC laws and regulations. We have since rectified the housing provident fund contributions, and have been making full contributions in compliance with applicable requirements starting from February 2024. Based on (i) our Company has obtained written confirmations on from the competent social insurance authorities, and received the public credit information report issued by competent authorities, which confirm that our Company has not been subject to any administrative penalties for the non-compliance with employee benefit contribution; (ii) according to the Urgent Notice of the General Office of the Ministry of Human Resources and Social Security on Effectively Implementing the Essence of the Executive Meeting of the State Council and the Measures on the Stable Collection of Social Insurance Contributions (《人力資源社會保障部辦公廳關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) which was promulgated on September 21, 2018, and the Notice on Implementing Further Measures to Support and Serve the Development of the Private Economy (《關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued by the State Taxation Administration on November 16, 2018, local governmental authorities are prohibited from centralized collecting of historical unpaid social insurance premiums independently in order not to exert additional burden to the enterprises; (iii) during the Track Record Period and up to the Latest Practicable Date, our Company has not been subject to any social insurance and/or housing fund arrears recovery, rectification orders or penalties by the competent authorities; (iv) according to the communication with the competent social insurance and housing provident fund authorities, upon receiving an employee’s claim, they generally require the employer to pay the part that the employee fails to pay in full, rather than requiring the employer to make full contributions; (v) the assumption that there will be no material change to the relevant PRC laws, regulations and policies and the practice of the relevant authorities and there are no employee’s complaint or claim for contributions to social insurance and housing provident funds, our PRC Legal Advisor is of the view that the risk of us being subject to material administrative penalties by the relevant authorities is low.

Our Company has taken the following measures: (i) strengthen legal compliance training to our management team; (ii) enhance our internal control policy to manage our social insurance fund and housing provident fund contributions; and (iii) Dr. Liu Binlei will undertake to indemnify the Company if it is subject to any social insurance and/or housing fund arrears recovery, rectification orders or penalties by the competent authorities.

PROPERTIES

We are headquartered in Wuhan, China. We own and lease certain properties in various cities in China primarily to be used for manufacturing bases, R&D and office premises and dormitories.

The Property Valuation Report from Cushman & Wakefield set out in Appendix III to this document, sets out details of our selective property interests as of January 31, 2026. Cushman & Wakefield valued these property interests at an amount of RMB171 million as of January 31, 2026. Except for the property interests set forth in the property valuation report from Cushman & Wakefield, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of January 31, 2026.

Owned Land and Properties

As of the Latest Practicable Date, we owned land use rights with respect to three parcels of land in Wuhan, Ezhou and Shaoxing, China with land use right certificates, with a total gross land area of approximately 43,287 sq.m. We also owned one building in Ezhou, China with building ownership certificate with an aggregate gross floor area of approximately 3,222 sq.m. This building is primarily used for our early-stage R&D, manufacturing and quality management activities. As of the Latest Practicable Date, we are constructing additional facilities in Wuhan and Shaoxing, China. We have obtained the relevant land use right certificates, and expect to obtain the relevant building ownership certificates upon completion of construction and inspection.

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Leased Properties

As of the Latest Practicable Date, we had primarily 8 leased properties in China from Independent Third Parties with a total area of approximately 1,537.26 sq.m., used for R&D and office premises, and dormitories. The relevant lease agreements generally provide a duration of up to 12 months. Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, none of our leased properties in China had been registered and filed with relevant land and real estate management departments in China, which may expose us to potential fines if we fail to remediate after receiving any notice from the relevant PRC governmental authorities. Failure to complete the lease registration will not affect the legal effectiveness of the lease agreements according to PRC law, but the competent real estate administrative authorities may require the parties to the lease agreements to complete lease registration within a prescribed period of time, and failure to do so may subject the parties to fines from RMB1,000 to RMB10,000 for each of such non-registered lease agreements. As of the Latest Practicable Date, we were not aware of any notice or allegation of penalty from PRC government authorities for our failure on the registration of lease agreements. See “Risk Factors—Risks Relating to Our Operations—We are subject to risks associated with our owned or leased properties.”

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies primarily include employer’s liability insurance, clinical trial liability, and preclinical R&D expenses loss insurance. We believe that our insurance coverage is adequate to cover our key assets, facilities, and liabilities. See “Risk Factors—Risks Relating to Our Operations—We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we have obtained all requisite licenses, permits, approvals and certificates from the relevant government authorities that are material for our business operations in the PRC.

The following table sets forth details of selected material licenses and permits obtained by our Group as of the Latest Practicable Date:

License/Permit	Holder	Date of Grant	Expiry Date
Drug Manufacturing License (Category A) ¹	Our Company	August 4, 2023	August 3, 2028
Experimental Animal Use Permit	Our Company	December 26, 2023	December 25, 2028

Note:

- 1 We obtained the Category A drug manufacturing license in August 2023. The scope of the license covers (i) the recombinant human GM-CSF oncolytic HSV-II (OH2) injection (Vero cells) and (ii) the recombinant human PD-L1/CD3 bispecific antibody oncolytic HSV-II (BS006) injection (Vero cells), which together enable the Company to manufacture BS001 and BS006. To obtain this license, we are required to demonstrate that the Company (1) employs duly qualified pharmaceutical and engineering professionals, (2) maintains manufacturing premises, production facilities, and sanitary conditions that meet the standards applicable to the relevant products, (3) has in place a comprehensive quality assurance system and management framework, and (4) has established and implemented a full set of quality-control procedures covering the entire production cycle, including raw material procurement, manufacturing controls, quality testing, and product release. Holding this license allows the Company, upon obtaining the relevant marketing authorizations, to autonomously manufacture its drug products in the future.

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Our Company has complied, in all material respects, with all applicable laws and regulations and has obtained all required material licenses, permits, approvals and certificates in all applicable jurisdictions in all material aspects. None of our Company or the Directors were involved in any material litigation, arbitration or administrative proceedings during the Track Record Period and up to the Latest Practicable Date.

AWARDS AND RECOGNITIONS

The following table sets forth the major awards and recognitions we received as of the Latest Practicable Date. Notably, in 2024, our Company was recognized as a National “Specialized, Refined, Differential, and Innovative Little Giant” Enterprise (專精特新「小巨人」企業), an honor typically awarded to profitable companies, which reflects our Company’s exceptional technological strength despite its lack of profitability.

Year of Grant	Award/Recognition	Issuing Authority
2025	Hubei Provincial Oncolytic Virus Drug Pilot Platform (湖北省溶瘤病毒藥物中試平台)	Department of Economy and Information Technology of Hubei Province (湖北省經濟和信息化廳)
2025	Wuhan Oncolytic Virus Drug Pilot Platform (武漢市溶瘤病毒藥物中試平台)	Wuhan Science and Technology Innovation Bureau (武漢市科技創新局)
2025	2025 China Top 101 Innovative Pharmaceutical Companies (2025中國創新藥企TOP101)	PHARNEX (藥融圈)
2025	National Major Science and Technology Project (創新藥物研發國家科技重大專項)	China National Center for Biotechnology Development (中國生物技術發展中心)
2024	National “Specialized, Refined, Differential, and Innovative Little Giant” Enterprise (專精特新「小巨人」企業)	Ministry of Industry and Information Technology (工業和信息化部)
2024	2024 Top 100 Chinese Innovative Pharmaceutical Companies (2024中國醫藥創新企業百強)	Healthcare Executive (E藥經理人)
2023	China Oncolytic Virus Therapy Leadership Award (中國溶瘤病毒療法領導獎)	Frost & Sullivan
2023	Scientific and Technological Achievement Appraisal—Oncolytic Virus Technology Rated as Internationally Leading (科技成果評價—溶瘤病毒技術國際領先)	Beijing Guoke Yingchuang Technology Evaluation Co., Ltd. (北京國科盈創科技評估有限公司)
2023	National Key Research and Development Program “Frontier Biotechnology” initiative (國家重點研發計劃前沿生物技術重點專項)	China National Center for Biotechnology Development (中國生物技術發展中心)
2022	High and New Technology Enterprise (高新技術企業)	Science and Technology Department of Hubei Province (湖北省科學技術廳), Department of Finance of Hubei Province (湖北省財政廳) and Hubei Provincial Tax Service, State Taxation Administration (國家稅務總局湖北省稅務局)
2022	Hubei Provincial Major Science and Technology Special Project on Innovative Drug Research and Application for Major Diseases (湖北省重大疾病創新藥物研製及應用科技重大專項課題)	Department of Science and Technology of Hubei Province (湖北省科技廳)

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ENVIRONMENT, SOCIAL AND CORPORATE GOVERNANCE

Governance and 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 ESG risks that may impact our business, strategy and financial performance, and integrate considerations of ESG issues into our business, strategic and financial planning, in compliance with the recommendations made by the Environmental, Social and Governance Reporting Guide in Appendix C2 to the Listing Rules. Our Board is responsible for monitoring and enhancing compliance with ESG laws and regulations. Our management regularly reports to our Board on ESG matters, and our Board makes decisions regarding our policies and practices in alignment with ESG requirements. Our Board will continue to monitor, evaluate, and address ESG issues, overseeing the implementation of policies that promote ESG practices.

Environmental Protection

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

Wastes

We have established waste management procedures to ensure compliance with applicable waste-disposal regulations and to minimize environmental impact. We are committed to minimizing the environmental impact of our operations through comprehensive waste management practices. We have implemented a comprehensive exhaust-gas treatment system under which emissions are collected via the ventilation system and treated with high-efficiency filters, ozone generators, ultraviolet disinfection units, and activated-carbon adsorption before discharge, ensuring emissions remain well below regulatory limits. Our laboratory wastewater is subjected to high-temperature, high-pressure inactivation prior to discharge, and the effluent consistently meets stringent national standards. For biological and hazardous waste, we apply high-temperature, high-pressure inactivation, temporarily store such waste in dedicated storage areas, and regularly consign it to qualified third parties for disposal. The wastewater and solid waste generated during our in-house research and development process are pre-treated by our team through high-pressure sterilization and disinfection to meet corresponding standards before being handled by qualified third-party medical waste treatment companies.

Greenhouse gas emissions

Our greenhouse gas emissions are categorized into Scope 1, Scope 2, and Scope 3 emissions, which is categorized and defined according to Greenhouse Gas Protocol, a joint initiative of World Resources Institute (WRI) and the World Business Council for Sustainable Development (WBCSD) release in September 2001 and revised in March 2004. Scope 1 emissions are primarily small-scale and tied to our R&D processes and facilities. Scope 2 emissions mainly arise from the indirect emissions linked to the electricity we purchase to power our operations. Scope 3 emissions encompass indirect emissions that occur outside of Scope 2, primarily within our value chain. Our greenhouse gas emissions consist of Scope 1 and Scope 2 emissions. In response to the national carbon neutrality target, we are committed to actively reducing the greenhouse gas emissions produced in our operations.

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.

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	Year Ended December 31,	
	2024	2025
Resource consumption		
Electricity (<i>MWh</i>)	2,529	2,588
Water (<i>tons</i>)	2,920	8,121
Emission		
Hazardous waste (<i>tons</i>)	7.25	7.35

During the Track Record Period, our water consumption is 2,920 tons and 8,121 tons for 2024 and 2025. The high water consumption in 2025 was mainly due to the operations at the Company’s new Wuhan facility (approximately 40,000 square meters), where water was primarily used for construction, fire-fighting water storage and routine maintenance. We have conducted a comprehensive inspection and repair of our site’s water supply and drainage infrastructure, and implemented enhanced monitoring and maintenance procedures to prevent future leakage. We will perform regular maintenance and integrity checks of all utility and drainage systems.

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, manufacturing process, and waste management.

Targets and Measures

Targets

Following the ESG evaluation system standards in the PRC and the prevailing market practice adopted by industry pioneers, we aim to avoid or reduce the adverse environmental impacts arising from our operations. Upon [REDACTED], our Board will, at the beginning of each financial year, set targets for material ESG KPIs in accordance with the disclosure requirements under Appendix C2 to the Listing Rules and other applicable rules and regulations, including relevant national and industry environmental standards. Such KPI targets will be reviewed on an annual basis under the direct supervision of our Directors and senior management to ensure that they remain appropriate and aligned with the operational needs of our Company. In formulating these ESG-related KPI targets, we have taken into account our historical levels of resource consumption and waste discharge during the Track Record Period and have prudently considered our expected business expansion plans, with a view to striking an appropriate balance between business growth and environmental protection. We will continue to devote efforts to achieving our target of reducing our electricity and water consumption, as well as hazardous waste discharge, per thousand dollars of total manufacturing costs by 5% over the next three years.

Measures

We have adopted comprehensive measures to mitigate environmental impact from our business, strategy and financial performance, which we will continue to evaluate and improve in the future: (i) adopt exhaust gas treatment systems and install activated carbon filters to reduce emissions; (ii) increase the use of clean energy where feasible; (iii) utilise energy-efficient equipment in our operations; (iv) install sewage treatment systems to ensure compliant wastewater discharge; (v) require proper handling and disposal of solid waste in accordance with internal procedures; (vi) establish hazardous waste storage sites in accordance with applicable standards and implement a standardized hazardous waste management system; (vii) engage qualified third-party service providers for the disposal of solid and hazardous waste; (viii) remind employees to switch off

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lighting after work hours; (ix) maintain air-conditioning at moderate temperature settings; (x) conduct regular inspections of faucets to prevent water leakage; and (xi) display water-saving and power-saving reminders in prominent areas of our offices.

We believe that our annual costs of compliance with applicable environmental protection and health and safety laws and regulations were immaterial during the Track Record Period, and we do not expect such compliance costs to increase significantly going forward. To the best knowledge of our Directors, and after taking the necessary actions to achieve the aforementioned ESG goals, there will be no material financial or non-financial impact on our business or results of operations. However, as the requirements under these laws and regulations may change from time to time, we may not be able to accurately predict the costs associated with future compliance. See “Risk Factors—Risks Relating to Our Operations—We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

Climate Change

We believe that we are not susceptible to climate change. Moreover, we consider that potential changes to the regulations in the PRC regarding climate change will not adversely impact our business operations. We will continue to pay attention to risks regarding climate change and formulate emergency plans to safeguard us from climate change and extreme weather conditions, such as hurricane and rainstorms. As of the Latest Practicable Date, we had not experienced any material impact on our business operations or financial performance as a result of climate change or extreme weather conditions.

Preclinical and Clinical Study

We have implemented a series of measures to bolster laboratory and clinical trial safety while ensuring compliance with relevant regulations. These measures include the establishment and enforcement of internal policies and procedures aimed at clinical trial safety, starting with: (a) formulating a comprehensive R&D project management policy to oversee the entire lifecycle process of drug development, encompassing preclinical studies and clinical trials; (b) implementing guidelines pertaining to employee health and safety, environmental protection, and operational safety within laboratory settings; (c) monitoring adverse events associated with our drug candidates during clinical trials and maintaining accurate records of these events for each trial; (d) conducting analysis of collected adverse events and assessing associated safety risks; (e) reporting serious adverse events and potential safety risks; and (f) facilitating communication with relevant employees and CROs to ensure enforcement of clinical trial protocols.

Animal welfare and patient safety

Ethics form an essential component of our pharmaceutical R&D management framework. We strictly comply with applicable laws, regulations and ethical standards, including the World Medical Association’s Declaration of Helsinki and the Regulations for the Administration of Laboratory Animals. Our objective is to protect the legitimate rights and interests of human subjects and to ensure the welfare of laboratory animals. We comprehensively safeguard the rights of clinical trial participants, including their rights to informed consent, privacy and drug-use safety. All clinical trials are conducted in accordance with applicable regulatory requirements and based on informed consent from the participants. Meanwhile, we fully consider the welfare of laboratory animals involved in our experiments. We have established Standard Operating Procedures for the Ethical Review of Laboratory Animal Welfare to ensure that laboratory animals are afforded appropriate care throughout their lifecycle, including during transportation. Animals must be kept in conditions that are free from hunger, thirst and discomfort, and the management of all laboratory animals must be carried out in strict accordance with the relevant operational and technical procedures.

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Workplace Safety

We are dedicated to ensuring a safe working environment for our employees. We firmly believe that a safe and healthy workplace is not only crucial for the well-being of our employees but also indispensable for the sustainability of our business. We have implemented and upheld a comprehensive set of rules, standard operating procedures, and measures to ensure the health and safety of our employees. Our safety guidelines cover a range of areas including identifying potential hazards, safe practices, accident prevention, and procedures for reporting accidents. We ensure that our employees continually acknowledge their understanding of safety protocols as needed. Specifically, we regularly carry out emergency-management training for employees, provide staggered sessions to reinforce general emergency-management knowledge, and organize an annual on-site drill. We equip our facilities with necessary fire-protection equipment and personal protective equipment, and strengthen maintenance to keep such items in good standby condition. We designate personnel to conduct regular inspections for potential safety hazards, assign dedicated patrols for critical areas, and maintain records for routine production inspections.

Workplace Diversity

Within our Company, we are steadfast in our commitment to fostering an open and inclusive workplace that champions equality. We adhere to a corporate policy of hiring employees based solely on their merits, offering equal opportunities regardless of gender, age, race, religion, or any other social or personal characteristics. As of December 31, 2025, more than 63% of our total employees were female. Our employee management system operates on principles of fairness and transparency, and we actively work to enhance gender and age diversity within our workforce.

LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

As of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against our Company or any of our Directors which could have a material and adverse effect on the research and development of our drug candidates, our financial condition or results of operations. Potential future litigation or any other legal or administrative proceeding, regardless of the merit or outcome, is likely to result in substantial costs, diversion of our resources, and have a negative impact on our reputation and brand image, which in turn, would have negative impact on our business, financial condition, and results of operations. For potential impact of legal or administrative proceedings on us, please refer to the paragraphs headed “Risk Factors—Risks Relating to Our Operations—We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business, which could adversely affect our business, financial conditions, results of operations and reputation.” in this document. During the Track Record Period and up to the Latest Practicable Date, we had complied, in all material respects, with all relevant laws and regulations in the jurisdictions we operate in. We had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our Group’s business operations.

RISK MANAGEMENT AND INTERNAL CONTROL

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We recognize that risk management is critical to the success of our business operation. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to foreign currency, credit and liquidity risks that arise in the normal course of our business. See “Financial Information—Market Risk Disclosure” for a discussion of these market risks. We have implemented a comprehensive set of risk management

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policies that establish a framework for identifying, assessing, evaluating, and continuously monitoring key risks aligned with our strategic objectives. 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. Our Directors supervise the implementation of our risk management policies.

The following key principles outline our Group’s approach to risk management and internal control we plan to implement:

- Our audit committee will oversee, evaluate, and enhance the internal control system, which includes: (i) reviewing internal control and risk management policies and providing suggestions for improvement; (ii) engaging in discussions with management to evaluate the effectiveness of internal control and risk management policies, ensuring that management fulfills its duties in formulating effective policies; and (iii) analyzing material findings related to internal control and assessing the measures taken by management.
- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant teams in our Company; (iii) reviewing the relevant teams’ reporting on key risks and providing feedbacks; and (iv) supervising the implementation of our risk management measures by the relevant teams.
- The relevant departments within our Company bear the responsibility of implementing our risk management policy and executing day-to-day risk management practices. To standardize risk management procedures across our organization and ensure a consistent level of transparency and risk management performance, these teams will: (i) collect information regarding the risks associated with their respective operations or functions; (ii) conduct comprehensive risk assessments, encompassing the identification, prioritization, measurement, and categorization of all key risks that could impact their objectives; (iii) continuously monitor key risks pertinent to their operations or functions; (iv) implement appropriate risk responses when necessary; and (v) develop and maintain a suitable 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 internal control consultant (the “**Internal Control Consultant**”) to perform certain agreed-upon procedures (the “**Internal Control Review**”) in connection with the internal control during the period from July 2024 to December 2025 of our Company and our major operating subsidiaries in certain aspects, including entity-level controls, financial reporting and disclosure controls, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in July and August, 2025 and March 2026, identified internal control deficiencies and provided recommendation accordingly. We have adopted the corresponding remediation actions to improve the effectiveness of internal control system. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no further material findings identified in the process of the follow up review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company’s internal control.

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

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, environmental protection and occupational health and safety. For more information, see “— Environment, Social and Corporate Governance” in this section. We provide periodic training about these measures and procedures to our employees as part of our employee training program.
- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our employees are also required to regularly attend on-site and online training sessions to keep them informed of recent updates in the relevant laws and regulations.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect to financial reporting as well as oversees internal control procedures of our Group.
- 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 biopharmaceutical industry.