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OVERVIEW

We are a clinical-stage biotechnology company focusing on developing bispecific antibody therapeutics for broad cancer and autoimmune diseases. We develop our bispecific antibodies and TCEs by applying nearly a decade of experience in this field and using a differentiated toolbox of bispecific formats and CD3 binder panel technologies to which we have proprietary rights. We are leveraging our R&D strengths, our “plug-and-play” approach to antibody engineering — where our FIT-Ig design allows rapid assembly of new bispecifics by inserting any two parental antibody Fv sequences, without re-engineering the entire molecule, and our preclinical and clinical development strategy to generate a diverse and balanced portfolio and research pipeline. Since inception in 2015, we have discovered and developed multiple clinical-stage assets and built a rich preclinical pipeline in-house. Our pipeline comprises three clinical-stage drug candidates, including (i) our Core Product EMB-01 (targeting EGFR/cMET), with metastatic colorectal cancer (“**mCRC**”) as its lead indication, which is currently in Phase II development as monotherapy for third-line treatment and in Phase Ib development for use in combination therapy, (ii) two TCE-based key products EMB-06 (targeting BCMA/CD3) and EMB-07 (targeting ROR1/CD3), and (iii) four preclinical drug candidates, EM1032 (targeting ALPP(G)/CD3), EM1034 (targeting LY6G6D/CD3), EM1039 and EM1042.

Our bispecific and TCE pipeline. Our portfolio strategy is driven by a meticulous evaluation of several key factors, including our ability to harness multi-specific antibody engineering technologies, our biological and research expertise, the availability of preclinical and clinical evidence for targets, and the commercial potential of these targets. From the outset, we have focused on developing bispecific antibodies, utilizing our proprietary bispecific formats. These antibodies are designed to bind two distinct targets simultaneously, enabling mechanisms such as immune cell redirection, synergistic pathway blockade, or conditional activation. This dual-targeting capability enhances specificity and potentially offers a more favorable safety profile. We have consistently explored various bispecific mechanisms, including targeting co-expressed tumor cell targets (e.g., EMB-01 targeting EGFR/cMET), and TCEs (e.g., EMB-06 targeting BCMA/CD3). Our strategic emphasis on TCEs is a natural extension of our foundational approach. This focus is supported by their clear mechanism of action, our robust technology platforms (including our bispecific platforms and proprietary CD3 panel), the increasing number of globally approved TCEs, and the substantial commercial opportunities they present in treating solid tumors and autoimmune diseases.

Our pipeline development strategy. We recognize that our proprietary technology has the potential to generate an evolving number of high-potential assets that may exceed what a single biotech company can develop and commercialize independently. As such, our strategy is not a one-size-fits-all approach but rather a tailored plan for each asset, based on its therapeutic area, stage of development, and market potential. We intend to self-develop assets in key therapeutic areas where we have the internal capabilities and resources to manage clinical development and eventual commercialization, for example, late-line colorectal cancer, hematological cancer, or immunology diseases with high unmet need. This approach allows us to retain full ownership and capture the maximum potential value. For assets that fall outside our primary strategic

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focus or require significant capital beyond our current scope, we may pursue out-licensing arrangements. We may seek partners, such as major pharmaceutical companies, that have the substantial resources, global clinical development expertise, and commercial infrastructure to bring our drugs to market. In these partnerships, we leverage our partner’s bandwidth to advance the assets while participating in the economic benefits through milestone payments and royalties on future sales, thereby generating non-dilutive capital and mitigating our development risk. We may also enter into co-development arrangements with smaller, specialized partners or venture-backed NewCos. These collaborations allow us to leverage our partners’ unique territorial or strategic focus and share both the costs and the risks of development. This strategy enables us to efficiently advance assets in niche markets or indications.

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Below is a pipeline diagram setting forth our drug candidates:

Program ⁽⁶⁾	Target	Indication	Line(s) of treatment	Mono/Combo	PCC	IND-enabling	Phase I	Phase II	Phase III	Key Regulatory Authorities	Current Status/Upcoming Milestone	Rights	Partners
		Advanced/metastatic GI Cancers (CRC, HCC, gastric, biliary tract cancer)	≥3L	Mono						FDA, NMPA	Completed patient's enrollment in March 2025/Expected Phase Ib/II trial completion in Q4 2025	Global	/
★ EMB-01	EGFR/GMET	mCRC	≥3L	Mono						NMPA	IND approval from the NMPA in May 2025/Expected Phase I initiation around year end of 2025 ⁽⁶⁾	Global	/
		mCRC	2L, 3L	+Chemo						NMPA	IND approval from the NMPA in January 2024/Expected Phase I initiation pending interim data readout of Phase II mono	Global	/
★ EMB-07	ROR1/CD3	Solid tumors/relapsed or refractory lymphoma	≥3L/≥2L ⁽⁵⁾	Mono						NMPA	Dose-escalation still ongoing/Expected Phase I trial completion in Q1 2026	Global	/
		DLBCL	1L, 2L	Combo ⁽⁶⁾						NMPA	IND approval in September 2025/Expected study initiation in Q2 2026	Global	/
EMI1032	ALPP(G)/CD3	Solid tumors	/	TBD						/	Expected IND submission in Q1 2026	Global	/
EMI1034	LY6G6D/CD3	Solid tumors	/	TBD						/	Expected IND submission in Q4 2026	Global	/
★ EMB-06 ⁽⁵⁾	BCMA/CD3	SLE, gMG	Relapsed/Refractory	Mono						NMPA	Ongoing Phase I trials in SLE and gMG sponsored by Candil ⁽⁵⁾	China ⁽⁵⁾	Candil
		TED	/	Mono						NMPA	Ongoing Phase I trial in TED sponsored by Candil ⁽⁵⁾	China ⁽⁵⁾	Candil
EMI1039	Undisclosed trispecific TCE	Autoimmune diseases (B cell related)	/	TBD						/	Expected initiation of IND-enabling studies by Q2 2026	Global	/
EMI1042	Undisclosed TCE	Autoimmune diseases (Inflammatory cell related)	/	TBD						/	Expected initiation of IND-enabling studies by Q2 2026	Global	/

■ TCE Programs
 ■ Non-TCE Programs
 ★ Core Product
 ☆ Key Product

Abbreviations: 1L = First-line, 2L = Second-line, 3L = Third-line, Chemo = Chemotherapy, Combo = Combination Therapy, CRC = Colorectal Cancer, FDA = U.S. Food and Drug Administration, GI = Gastrointestinal Cancer, gMG = Generalized Myasthenia Gravis, H1 = First Half, H2 = Second Half, HCC = Hepatocellular Carcinoma, IND = Investigational New Drug, mCRC = metastatic colorectal cancer, Mono = Monotherapy, NA = Not Applicable, NMPA = National Medical Products Administration of the PRC, PCC = Preclinical Candidate Compound, Q1 = First Quarter, Q4 = Fourth Quarter, SLE = Systemic Lupus Erythematosus, TBD = To Be Determined, TCE = T-cell Engager, TED = Thyroid Eye Disease

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Notes:

- (1) All of our drug candidates are developed in-house.
For each drug candidate, our clinical development typically begins with a dose escalation trial to characterize safety, tolerability, and pharmacokinetics and to identify a recommended dose or dose range, where multiple patient groups across different tumor types or indications are enrolled to assess both safety and efficacy of the drug candidate. Where scientifically justified and permitted by protocol and ethics approvals, we may include expansion cohorts that enroll patients with predefined tumor types or biomarker-defined subpopulations to obtain preliminary signals of activity and to refine the target population. Advancement to later-stage development for any indication is not automatic and is contingent on prespecified, candidate-specific criteria (e.g., acceptable safety profile, exposure consistent with target engagement, and clinically meaningful antitumor activity per RECIST or indication-appropriate criteria), as well as on the availability of validated patient selection strategies. In addition, progression is subject to the requirements of Competent Authorities, including protocol amendments, alignment on the recommended Phase 2 dose, acceptance of the proposed indication and endpoints, and, where applicable, fulfillment of CMC, nonclinical, and safety monitoring conditions. Based on the results from this trial, we determine which indications to prioritize for advancement into later-stage clinical development.
- (2) We granted Candid an exclusive, royalty-bearing and sublicensable license under our applicable controlled patents and know-how to research, develop, manufacture and commercialize EMB-06 for the diagnosis, treatment or prevention of all human and non-human diseases outside China (including Hong Kong, Macau and Taiwan) (the “Candid Territory”). We retain the right to research, develop, manufacture and commercialize EMB-06 for the diagnosis, treatment or prevention of all human and non-human diseases in China (including Hong Kong, Macau and Taiwan) (the “EpimAb Territory”).
Under the EMB-06 License and Collaboration Agreement, we agreed to wind down our ongoing multi-center Phase I/II clinical trial of EMB-06 for oncology indications according to a wind-down plan. The wind-down plan involves wrapping up the Phase I dose-escalation portion of the Phase I/II clinical trial of EMB-06 for relapsed or refractory multiple myeloma, not pursuing Phase II dose-expansion portion, and notifying trial sites in China and Australia of the study closure. The rationale for this wind-down is to avoid any potential impact of the ongoing oncology trial in China on Candid’s conduct of clinical trials of EMB-06 in autoimmune indications and its future regulatory submissions in the Candid Territory. Following the wind-down, we will not develop or license EMB-06 in the EpimAb Territory until Candid initiates a pivotal clinical trial of EMB-06. Upon Candid’s initiation of a pivotal clinical trial of EMB-06, we will initiate pivotal trial in China by either running an independent pivotal trial or joining a global pivotal trial of Candid by adding patients from China in antibody-related autoimmune diseases/indications — diseases in which pathogenic autoantibodies produced by the patient’s immune system directly drive tissue damage or pathophysiological changes. We currently do not expect to pursue further development of EMB-06 in China in oncology in the near term.
The EMB-06 License and Collaboration Agreement provides that, upon Candid’s initiation of a pivotal clinical trial of EMB-06, we may initiate studies for our own regulatory submissions in the EpimAb Territory and are responsible for them at our own expense. Candid is responsible for the development of EMB-06 in the Candid Territory at its own expense. Nonetheless, in order to accelerate early clinical development of EMB-06 worldwide, Candid may, although it does not have any commercialization rights in China, conduct clinical trials in the EpimAb Territory for the purposes of obtaining regulatory approval in the Candid Territory. Therefore, to expedite worldwide development of EMB-06 and in compliance with the EMB-06 License and Collaboration Agreement, Candid is conducting clinical trials of EMB-06 for systemic lupus erythematosus (SLE), generalized myasthenia gravis (gMG) and thyroid eye disease (TED) in China, as well as multiple investigator-initiated studies. We will have access to all data generated by Candid. We may use such obtained data to support our own regulatory submissions in the EpimAb Territory. This arrangement allows us to leverage global development efforts while ensuring that our development and regulatory activities in China remain under our control and consistent with our contractual rights. For clarification, we will be the named marketing authorization holder of the regulatory approvals of EMB-06 in the EpimAb Territory. See “Business — Our Drug Candidates — Our Clinical-Stage Drug Candidates — EMB-06 (BCMA/CD3), Our Key Product — Clinical Development Plan” for details.
- (3) Including Hong Kong, Macau and Taiwan.

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- (4) Upon completion of Phase I portion of a first-in-human Phase I/II trial of EMB-01 for advanced/metastatic solid tumors in September 2021, we initiated a Phase Ib/II trial to evaluate EMB-01 monotherapy in gastrointestinal cancers, including gastric, hepatocellular, biliary tract and colorectal cancer, in October and December 2021 in the United States and China, respectively. In this trial, EMB-01 monotherapy demonstrated efficacy signals and manageable safety in heavily treated mCRC patients. Based on encouraging interim trial results, we submitted an IND application for a Phase II trial of EMB-01 monotherapy in the third-line mCRC with the NMPA in March 2025 and received the IND approval in May 2025. We expect to initiate this Phase II clinical trial around year end of 2025.
- (5) In the Phase I clinical trial of EMB-07 monotherapy for solid tumors and relapsed/refractory lymphomas, patients in the solid tumor cohort were generally enrolled at later lines of therapy following exhaustion of standard treatment options; patients in the relapsed/refractory lymphoma cohort generally had ≥ 2 or ≥ 3 prior lines of treatment.
- (6) EMB-07 is currently being evaluated in a platform trial across multiple combination regimens, including (i) EMB-07 with R-CHOP (rituximab, cyclophosphamide, vincristine, doxorubicin, and prednisone) as a first-line treatment, as well as several second-line regimens including (ii) EMB-07 with R-GemOx (rituximab, gemcitabine, and oxaliplatin), (iii) EMB-07 with rituximab and polatuzumab (chemo-free), (iv) EMB-07 with rituximab, lenalidomide, and zanubrutinib (chemo-free), and (v) EMB-07 with rituximab and tucidinostat.

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Our Core Product. Our Core Product, EMB-01, is among the first EGFR/cMET bispecific antibodies globally to enter Phase II trials for metastatic colorectal cancer (“**mCRC**”). EMB-01 is a tetravalent bispecific antibody that simultaneously targets EGFR and cMET, designed to block signaling crosstalk between these receptors and induce co-degradation of both targets, effectively overcoming resistance to single-target therapies. In a Phase Ib/II study with heavily pretreated mCRC patients, it has demonstrated encouraging efficacy signals results. As of March 6, 2025, among 44 evaluable patients, 29 were with left-sided, RAS/RAF wild-type mCRC, seven achieved partial response (24.1% ORR) and 17 achieved stable disease (including 11 tumor-shrinking stable disease), resulting in a disease control rate (“**DCR**”) of 82.8%. The median duration of response (“**DOR**”) for six confirmed responders was 32 weeks, with two partial responses still on treatment at data cutoff. Among the remaining evaluable patients with more challenging baseline characteristics (e.g., right-sided, RAS/RAF mutant), the DCR reached 46.7%. EMB-01 also demonstrated a tolerable safety profile at doses up to 1,600 mg once weekly.

Our key products. Building on our momentum, we continue to expand the frontier of bispecific antibodies by advancing a number of TCE assets, particularly our two key products, EMB-06 and EMB-07, both in Phase I clinical stage as of the Latest Practicable Date. EMB-06, a BCMA/CD3 bispecific antibody rationally designed and developed for the treatment of relapsed/refractory multiple myeloma (“**R/R MM**”), has shown minimal cytokine release syndrome while maintaining robust anti-tumor activity in its preclinical studies. These preclinical results have translated into strong clinical outcomes, with our Phase I study of EMB-06 in relapsed or refractory (“**R/R**”) MM patients demonstrating relatively low hematologic toxicity and an only 25% incidence of cytokine release syndrome (all Grade 1 or 2), differentiating EMB-06 from all competitors. At higher dose levels (from 120 mg to 300 mg), EMB-06 achieved an overall response rate (ORR) of 91.7% and a complete response rate of 33.3%. Recent clinical data and collaborations also suggest a bright future for BCMA-targeting assets in B-cell-related autoimmune diseases, according to Frost & Sullivan. We further developed EMB-07, a bispecific antibody targeting both CD3 and the novel target ROR1. *In vivo* studies showed that EMB-07 is well tolerated and induces very low cytokine release at a relatively higher dose level (50 mg/kg).

Our preclinical assets. Beyond EMB-06 and EMB-07, we continue to leverage our technology platforms and expertise to develop optimized TCEs against underexplored tumor targets and other indications with high unmet needs. Our strategy, initiated with our clinical-stage assets EMB-06 and EMB-07, has now been expanded to include preclinical programs. EM1032, utilizing our FIT-Ig platform and CD3 technology, targets ALPP(G) to potentially address the significant medical needs of platinum and ADC-resistant ovarian cancer patients. Preclinical data indicated activity against tumors in ALPP(G)-ADC resistant ovarian cancer models, highlighting its high market potential, as approximately 50% ovarian cancers express ALPP(G) which is also expressed in lung and pancreatic cancers. Another asset, EM1034, is a TCE targeting the novel marker LY6G6D expressed in CRC. Preclinical study showed minimized cytokine release syndrome potential. Further, our KLK2/CD3 TCE candidate developed in-house has attracted market interest and was recently out-licensed to Juri, a biotech portfolio company incubated by TCG Labs Soleil, further validating the potential of our TCE pipeline in oncology. Beyond oncology, we are also exploring TCEs to address unmet needs in immunology, such as autoantibody-related immunology disorders.

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Our plug-and-play technology toolbox. At the core of our R&D success lies a suite of proprietary technology platforms designed to overcome the limitations of conventional bispecific antibody development. Our patented FIT-Ig (fabs-in-tandem immunoglobulin) platform features a unique linker-free, non-mutated, and tetravalent bispecific format that enables easy and fast creation of new bispecific antibodies by simply combing parts from two validated antibodies, allowing for a plug-and-play approach to multiple different targets, whereby a FIT-Ig bispecific molecule can be efficiently generated by incorporating any two parental antibody Fv sequences from existing monoclonal antibodies, without the need for extensive engineering or complicated procedures. This enables the rapid development of bispecific candidates from existing monoclonal antibodies in an average of four to six weeks. The FIT-Ig platform is the only bispecific antibody technology globally that does not require any amino acid mutations and does not contain linked peptide chains or non-antibody sequences, according to Frost & Sullivan. While there are other similar technical solutions for bispecific antibody design currently available in the market, the FIT-Ig platform distinguishes itself through its unique approach of maintaining the native antibody structure without introducing extraneous sequences or mutations. However, comparable platforms, including 1+1 bivalent IgG-like and 2+2 tetravalent formats, also support modular assembly and can achieve similar development timelines. In addition, the 2+2 valency of FIT-Ig entails practical clinical trade-offs: (i) stronger target-mediated drug disposition may shorten systemic exposure and reduce dosing intervals or necessitate higher doses to maintain efficacy; (ii) increased avidity can promote receptor clustering, which may heighten on-target toxicities or inflammatory responses in sensitive pathways; (iii) the larger molecular size may impact tissue penetration, potentially leading to suboptimal activity in poorly perfused or dense solid tumors; and (iv) confirmation of correct tandem Fab assembly and epitope access may require additional, platform-specific assays, which can add development steps and delay clinical readiness if misassembly or suboptimal epitope orientation is detected. Complementing the FIT-Ig platform is our MAT-Fab (monovalent asymmetric tandem fab) platform, a proprietary bivalent alternative format that is particularly suitable for certain targets such as ROR1, which enabled us to develop a more optimized ROR1 TCE, EMB-07. Additionally, we also have in-house antibody engineering expertise to develop and utilize other bispecific or multi-specific platforms as needed to create more optimized drug candidates. Together, these platforms synergistically integrate with our CD3 antibody panel, a proprietary collection of CD3 engaging antibodies that (i) utilize a common binding epitope, (ii) offer a range of binding affinities from double digit nanomolar to single digit micromolar in terms of dissociation constant (Kd), and (iii) are cross-reactive to non-human primates for toxicology testing. This proprietary technology toolbox enables the efficient generation and development of TCEs for each tumor-associated antigen, offering flexible combinations of formats and affinities to optimize therapeutic potential.

Our strategic collaborations. Since the end of 2023, we have forged multiple global out-licensing collaborations, representing a total deal value exceeding US\$2.1 billion, ranking the second globally in the TCE field according to Frost & Sullivan. Our strategic collaborations with partners are pivotal to accelerating our vision. In immunology, we have granted Almirall a license to leverage our FIT-Ig platform technology for the development of bispecific antibodies. As of the Latest Practicable Date, Almirall has exercised an option for selected

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FIT-Ig molecules and entered into a product family license agreement with us, further reinforcing the broad applicability and commercial potential of our platform. Additionally, our collaboration with Vignette Bio, Inc. (later acquired by Candid) to advance EMB-06 outside of China (including Hong Kong, Macau and Taiwan) represents a high-value alliance with a total potential deal value of up to US\$635 million, validating both the potential of our platform and our ability to structure and execute complex global partnerships. Further, we have partnered with Candid in a strategic research collaboration to discover and develop TCE program candidates for various autoimmune indications, demonstrating the versatility of our technology in addressing medical needs. Beyond immunology, we have entered into an out-licensing agreement with Juri on a KLK2/CD3 TCE developed in-house with a total potential deal value of up to US\$210 million, further validating the potential of our TCE pipeline in oncology. We strategically balance regional focus with worldwide reach, ensuring maximized market potential while advancing the development of our pipeline through high-impact collaborations. The relevant licensed products and the application of the underlying technologies in each of our collaboration arrangements with Candid, Juri, and Almirall are not related to EMB-01, our Core Product, or EMB-07, our key product. We anticipate that existing collaboration and out-licensing arrangements may contribute to our revenue in the future through development- or regulatory-dependent milestone payments and, if commercialized by our partners, royalties based on such sales. These arrangements provide a non-dilutive source of funding for ongoing research and development efforts. While these collaboration-related revenue streams may, over the life of the agreements, become an increasingly important component of our consolidated revenue, they remain inherently uncertain and contingent on outcomes outside our control, and are expected to remain supplementary to our primary R&D-focused business model.

Our development and collaboration strategy. We advance our pipeline through a strategy that prioritizes the self-development of key programs, complemented by selective licensing and co-development arrangements. For indications and territories that are core to our long-term positioning, we seek to progress our drug candidates through clinical development and potential commercialization ourselves. In parallel, we pursue collaboration opportunities with leading global biopharmaceutical companies where such partnerships can accelerate development timelines, broaden geographic reach, enhance commercialization capabilities or allow us to monetize non-core or geographically non-strategic rights. This strategy reflects our assessment of program-specific development costs, regulatory pathways, geographic priorities, and commercialization requirements, and enables us to allocate resources efficiently while diversifying development risk across our portfolio. Revenue that may arise from collaboration, out-licensing or co-development arrangements typically comprises milestone payments contingent on future development or regulatory progress and royalties based on potential future commercialization by collaboration partners. These revenue streams are supplementary to our core R&D activities and, given their contingent and non-recurring nature, do not affect our qualification as a biotech company seeking a [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules, as of the date of this document. We did not generate any material revenue from product sales during the Track Record Period, and our primary business model remains focused on the discovery and development of innovative drug candidates.

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OUR STRENGTHS

Research-Led Bispecific Antibody Developer Advancing T-Cell Engager Therapeutics

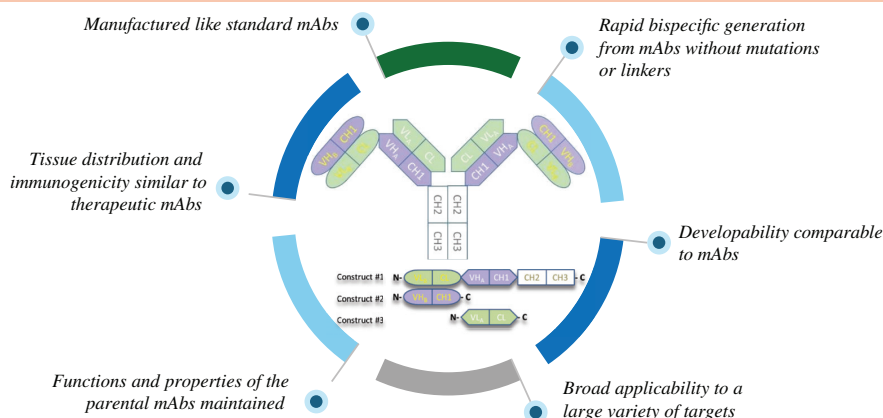
We focus on developing TCEs in the field of bispecific antibody therapeutics by leveraging our extensive experience and advanced toolbox of bispecific formats and CD3 binder panel technologies.

Our Bispecific Format Toolbox: FIT-Ig Platform

Bispecific antibodies represent a significant advancement in therapeutic antibody technology, overcoming the limitations of monoclonal antibodies by simultaneously binding to two different antigens. This dual binding could enhance therapeutic efficacy by enabling synergistic mechanisms of action that are not achievable by monoclonal antibodies, such as trans binding and colocalization of two cells. Our in-house developed FIT-Ig platform employs a unique approach by rearranging the DNA sequences of two monoclonal antibodies into three constructs, co-expressed in mammalian cells as depicted in the graph below. The symmetric arrangement of full-length antibody domains eliminates the need for Fc mutations, single-chain variable fragments, linkers, or peptide connectors, and yields tetravalent bispecific antibodies with four active and independent antigen binding sites. The FIT-Ig platform generates bispecific antibodies with preserved Fc functionality in a plug-and-play fashion, whereby a FIT-Ig bispecific molecule can be efficiently generated by incorporating any two parental antibody Fv sequences from existing monoclonal antibodies, without the need for extensive engineering or complicated procedures. This enables us to address a broad range of indications and optimize therapeutic designs for improved safety, efficacy, and manufacturability.

Proprietary FIT-Ig Platform: Optimal Molecular Design Drives Efficient Development of Bispecifics Antibodies

FIT-Ig is the only linker-free and non-mutated bispecific platform technology that allows plug-and-play of different targets with one format

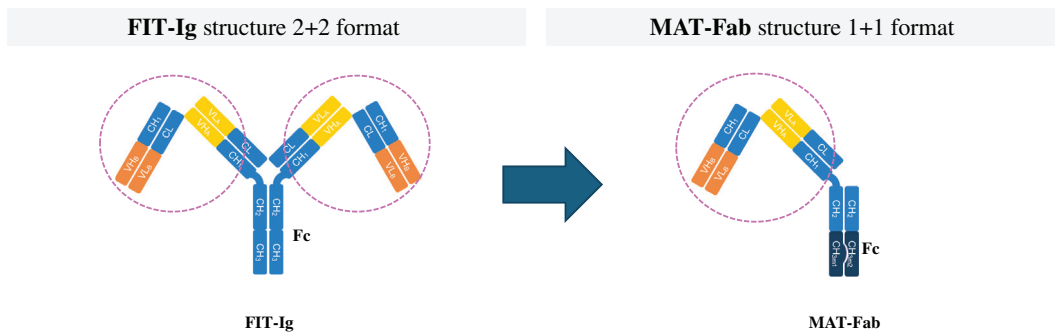


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Our Bispecific Format Toolbox: MAT-Fab Platform

Complementing our FIT-Ig platform, the MAT-Fab platform produces bispecific antibodies in a bivalent format, enhancing affinity for tumor-associated antigens while minimizing off-target binding. This design is crucial for targets requiring controlled avidity, such as ROR1 in solid tumors, and has enabled us to advance EMB-07 to its current clinical stage.

By Fabs-In-Tandem: MAT-Fab is a 1+1 Design Derived From FIT-Ig Platform



Our CD3 Binder Panel Toolbox

We have developed robust technological capabilities and platforms to address challenges towards creating an optimal TCE. For details of current challenges and entry barriers in developing TCE, see “Industry Overview — TCE: Redefining Immune Modulation for Precision Therapy in Cancer and Autoimmune Diseases.” Our experience in developing clinical-stage bispecific antibodies using multiple formats, such as FIT-Ig (e.g., EMB-06) and MAT-Fab (e.g., EMB-07), combined with our antibody engineering expertise, enables us to design and develop TCEs using multiple bispecific antibody formats. To tackle the crucial challenge of fine-tuning CD3 binding affinity, we have developed a proprietary CD3 binder panel with a common CDR binding region, embedding humanized sequences to minimize anti-drug antibody (“ADA”) potential, as well as ensuring they can bind to non-human primate T cells for good laboratory practice-compliant toxicity studies, and with a range of binding affinities varying from double-digit nanomolar to single-digit micromolar. The proximal arrangement of the T-cell and antigen binding domains in FIT-Ig and MAT-Fab, called cis-configuration, can enable potent T-cell activation at reduced CD3 affinity thresholds, minimizing non-specific CD3 engagement which reduces the risks of cytokine release syndrome. Importantly, this configuration introduces silenced Fc function, which are critical for preserving immune cells and tumor cytotoxicity. CD3 affinity can influence the balance between tumor cell killing and cytokine release. There is no single standardized “optimal” CD3 affinity across all TCEs due to the limited breadth of available studies and variability related to tumor targets, binding epitopes and TCE architectures. To accommodate this, we utilize a ready-to-use panel of humanized CD3 binders covering varied affinity levels and construct multiple prototype TCEs that differ by the CD3 binder sequence. Efficacy and cytokine release are then assessed in cell-based systems and animal models, and the final candidate is selected

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by jointly considering target cell lysis activity and cytokine levels. This program-specific workflow enables tailoring of TCEs with the goal of optimizing efficacy and safety, and has been successfully translated to clinical-stage development in our EMB-06 program. By tuning affinity and valency, our platforms allow a tailored design of TCE to optimize efficacy and safety.

Utilizing our technology toolbox, we can rapidly develop multiple versions of TCEs for a tumor-associated antigen of interest, with different combinations of bispecific antibody formats and CD3 binding affinities at an early research stage. Our experienced R&D team efficiently identifies the most promising TCE candidate(s) to advance into late research and clinical stages. Our approach sets us apart in the competitive landscape, positioning us as a force among TCE developers globally.

Clinical Validation of Our Technology Toolbox

Our pipeline features a portfolio of clinical and preclinical-stage drug candidates with a strategic focus on TCE therapeutics. Our bispecific assets, including our Core Product EMB-01 (EGFR/cMET) and two key products, EMB-06 (BCMA/CD3) and EMB-07 (ROR1/CD3), have advanced into clinical development, demonstrating our ability to swiftly translate innovation into the clinical applications. EMB-01 is among the earliest EGFR/cMET bispecific antibodies globally to enter Phase II trials for CRC. Our clinical-stage assets exhibit encouraging efficacy and safety profiles, reaffirming our dedication to delivering therapies that address medical needs. Building on this foundation, we continue to push the boundaries of bispecific antibody development by progressing further TCE assets into clinical development.

EMB-01 Among the Earliest EGFR/cMET Bispecific Antibodies to Advance into Phase II Trials for CRC

EMB-01, our Core Product, is a tetravalent bispecific antibody that simultaneously targets EGFR and cMET. It is designed to block signaling crosstalk between these receptors and induce their co-degradation, effectively overcoming resistance to single-target therapies. As of the Latest Practicable Date, there was no EGFR/cMET bispecific antibody approved or marketed globally for the treatment of CRC. Amivantamab, developed by Janssen, is the first EGFR/cMET bispecific antibody approved globally for the treatment of NSCLC and is also being evaluated in Phase III clinical trials for CRC. EMB-01 is among the earliest EGFR/cMET bispecific antibodies globally to have advanced into Phase II clinical trials for CRC.

CRC is a type of cancer that originates in the colon or rectum, and parts of the large intestine. It often begins as a polyp on the inner lining of the colon or rectum, which can develop into cancer over time. CRC is one of the most prevalent cancers worldwide, causing significant morbidity and mortality if not detected and treated early. In 2024, there were more than two million new cases of CRC globally, making it the third most common cancer worldwide. The market potential for CRC treatments in China is substantial, driven by the increasing prevalence of the disease and the need for more effective therapies. CRC is the second most commonly diagnosed malignancy and the fourth leading cause of cancer-related

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modality in China in 2024. In 2024, China reported approximately 542.4 thousand new cases of CRC, making it the country with the largest number of CRC cases globally. The rising incidence of CRC in China is a significant driver for the market. The CRC drugs market in China was valued at around US\$3.4 billion in 2024 and is projected to reach US\$10.8 billion by 2034, exhibiting a CAGR of 8.7%.

Current therapies for CRC face several limitations, primarily due to the necessity of tailoring treatment based on specific genetic mutations. For instance, tumors harboring RAS mutations (e.g., KRAS, NRAS) can demonstrate resistance to EGFR inhibitors such as cetuximab and panitumumab. Additionally, RAF mutations (e.g., BRAF V600E), characterized by aggressive progression and poor prognosis, often requires combination approaches involving BRAF and MEK inhibitors. Furthermore, microsatellite instability-high (MSI-H) mutations respond well to immune checkpoint inhibitors, but their efficacy can be limited in microsatellite stable (MSS) population, which comprises the majority of cases. These molecular distinctions underscore the challenge of treatment selection, as the heterogeneous nature of CRC demands precision medicine approaches that integrate targeted therapies while addressing resistance mechanisms and optimizing therapeutic durability.

Designed in our FIT-Ig platform, EMB-01 is structured in a way that simultaneously binds to both EGFR and cMET on the same cell surface. EMB-01 can thus efficiently block EGFR and cMET signaling crosstalk while inducing internalization and degradation of both receptors — an outcome unattainable with single-target monoclonal antibodies or combinations thereof. This mechanism of action not only inhibits tumor growth but also counteracts resistance pathways driven by EGFR or cMET signal transduction, which often is the cause of resistance to current EGFR therapies used for treatment of mCRC. Additionally, EMB-01 enhances tumor cell elimination through antibody-dependent cellular cytotoxicity, further strengthening its antitumor potential. These advantages position EMB-01 as a therapeutic option for patients with CRC who have gone through standard first- and second-line therapy.

EMB-01 has demonstrated encouraging efficacy signals in its Phase Ib/II study in heavily pretreated mCRC patients. As of March 6, 2025, among 44 evaluable patients in this study, 29 patients had left-sided, RAS/RAF wild-type mCRC. For the 29 patients, seven achieved partial response (24.1% ORR) and 17 achieved stable disease (including 11 tumor-shrinking stable disease), resulting in a DCR of 82.8%. The median DOR for six confirmed responders was 32 weeks, with two partial responses still on treatment at data cutoff. In the remaining evaluable patients who have more difficult baseline characteristics (e.g., right-sided, RAS/RAF mutant), the DCR reached 46.7%. EMB-01 has also demonstrated a tolerable safety profile at 1,600 mg once weekly.

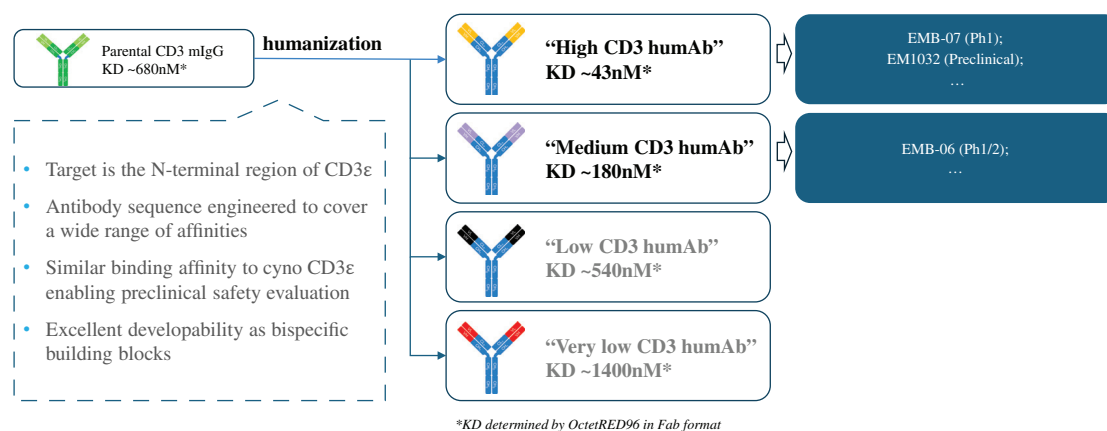
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Differentiated Pipeline with Strategic Focus on CD3 TCEs, Seizing the Frontier in Cancer and Autoimmune Disease Therapies

Our technologies aim to provide safer and more effective TCEs with improved therapeutic windows. We have developed a differentiated and systematic approach to creating a comprehensive CD3 panel, addressing one of the most significant challenges associated with TCE therapies — cytokine release syndrome.

Utilizing our platforms, we can optimize CD3 affinity and the required valency to find the right balance between optimal T-cell toxicity and minimal cytokine release. In addition, TCEs generated in our formats are “switched off” in the absence of targets, preventing cytokine release when merely injected into the body, and “switched on” in the presence of targets where the T-Cells are activated. Our tailor-made TCEs result in comparable efficacy to top competitors while offering differentiated safety profiles, including reduced cytokine release syndrome, neurotoxicity, and ICANS.

Our strategy has enabled the efficient generation of a comprehensive library of TCE candidates for each tumor-associated antigen, facilitating rapid screening and selection of the promising molecules. FIT-Ig provides a higher valency (tetraivalent) for potentially more specific binding as well as higher avidity, while MAT-Fab offers a lower valency (bivalent) for situations where fewer binding sites may be advantageous. This strategic approach allows us to fine-tune the binding properties of our TCEs, ensuring that tumor-associated antigen/CD3 affinity combinations can effectively target and engage tumor-associated antigens while minimizing off-target effects and optimizing therapeutic windows. Additionally, our approach enhances key drug properties such as extended half-life and improved biodistribution. These enhancements ensure that our TCEs achieve superior target engagement and therapeutic durability, providing sustained anti-tumor activity.



Guided by our insights into CD3 TCEs, we have developed a differentiated pipeline encompassing a wide range of tumor-associated antigen/CD3 affinity combinations, including EMB-06, EMB-07, EM1032 and EM1034. See “— Our Drug Candidates” for more details.

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Bispecific Antibody Clinical Development Capabilities Compounded with Strategic and Value-enhancing Partnerships

Ten years ago, under the leadership of our founder Dr. Chengbin Wu, our Company was established with a clear strategic vision: to overcome the technical barriers in bispecific antibody development and establish a leading position in this field. At the time of our inception, the bispecific antibody technology landscape in China was relatively underdeveloped, with many advanced technologies owned by biotech companies overseas. Recognizing the need to break through these barriers, we focused on developing our proprietary FIT-Ig technology platform. This platform, along with subsequent developments, has been a crucial foundation for our Company, making us one of the few companies in China with an original bispecific technology platform that has global intellectual property rights. Over the past decade, driven by our commitment to scientific rigor, we have established an integrated in-house R&D platform that covers target selection and validation, drug discovery, high-throughput screening, molecule design, preclinical studies, CMC and IND-enabling capabilities. As of September 30, 2025, our R&D team comprised 47 members with profound expertise in T-cell signaling, disease biology, and a wealth of experience spanning early-stage drug discovery, preclinical research, clinical development, and CMC processes.

Our integrated R&D platform enables us to effectively select novel targets, optimize molecule structure design and accelerate the drug development process. We are further exploiting the integration of FIT-Ig and MAT-Fab formats with CD3 binders to develop TCEs with optimal efficacy and safety profiles, including EMB-06, EMB-07, and discovery- and preclinical-stage candidates for several new targets. As a testament to our R&D competencies, as of the Latest Practicable Date, we have developed a pipeline of seven drug candidates in-house, with 21 IND approvals and acknowledgments from the NMPA, FDA and TGA. As of the Latest Practicable Date, around the globe, we owned 57 issued patents, 76 pending patent applications (including seven pending PRC patent applications, nine pending U.S. patent applications, and 60 pending patent applications in other jurisdictions), enabling us to tap into the overseas market and maximize the commercial value of our drug candidates.

Rooted in the strength of our pipeline assets and the data performance they have demonstrated, since the end of 2023, we have forged multiple out-licensing collaborations, representing a total deal value exceeding US\$2.1 billion, ranking the second globally in the TCE field according to Frost & Sullivan. Our partnership with Candid aims to discover and develop TCEs for autoimmune indications, leveraging our scientific expertise and antibody design capabilities. This collaboration includes an upfront payment and potential milestones totaling over US\$1.0 billion, validating the versatility and promise of our proprietary bispecific platforms. Additionally, in collaboration with Candid, we are advancing EMB-06, a BCMA/CD3 bispecific antibody, for development and commercialization outside of China (including Hong Kong, Macau and Taiwan). This partnership, with a total potential deal value of up to US\$635 million, highlights the clinical potential of EMB-06 in treating R/R MM and autoimmune diseases. Further, our collaboration with Almirall focuses on the development of innovative therapies for dermatological conditions utilizing our FIT-Ig technology, further demonstrating the broad applicability and impact of our technology platforms. More recently, we have entered into an out-licensing agreement with Juri on a KLK2/CD3 TCE developed in-house with a total potential deal value of up to US\$210 million, further validating the potential of our TCE pipeline in oncology.

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Seasoned Leadership Team with a Proven Track Record of Execution Excellence

We are led by a management team celebrated for their complementary expertise and visionary outlook in bispecific antibodies and TCEs. With decades of R&D and leadership experiences at major pharmaceutical companies, our executives bring a wealth of knowledge in preclinical research, CMC process development, and bispecific antibody and TCE drug clinical trials.

Dr. Chengbin Wu, our founder and chief executive officer, brings over 20 years of biopharma experience in biologics drug research and innovation, antibody engineering, and project leadership from concept to regulatory filing. Before founding our Company, Dr. Wu served as the chief scientific officer and president of R&D at 3Sbio, a leading China-based biopharmaceutical company. He also held the position of Senior VP Biologics at Shanghai ChemPartner, where he established comprehensive biologics R&D capabilities. Earlier in his career, Dr. Wu was a Volwiler Associate Fellow at Abbvie, United States. He is the primary inventor of the FIT-Ig technology, a bispecific antibody platform for developing next-generation biologics therapies. Dr. Wu received his Ph.D. from the University of Georgia and completed his postdoctoral training at Harvard Medical School in immunology with a research grant from the Cancer Research Institute, New York, NY. His extensive expertise and proven track record in antibody development and biologics R&D significantly bolster our technological capabilities and strategic objectives.

Dr. Stephen Lensky, our chief business officer, brings over 20 years of experience in the pharmaceutical industry, including 15 years in business development. Previously, Dr. Lensky headed the Corporate Department for Strategic Transactions & Alliance Management at Boehringer Ingelheim GmbH, where he was responsible for the negotiation and management of all strategic transactions of Prescription Medicines (PM) Business. Prior to that, he led a group at Bayer responsible for all commercial licenses in Europe and emerging markets. Dr. Lensky holds a Ph.D. in Chemistry and has been a member of the BioFIT Steering Committee since 2014. Dr. Lensky has a strong track record in executing business development strategies and evaluating and implementing strategic collaborations. His extensive experience and leadership in these areas significantly bolster our business development endeavours and strategic goals.

Dr. Yonghong Zhu, our chief medical officer, brings over 20 years of experience in clinical development, translational and discovery research in multinational corporations and biotech companies. Before joining us, Dr. Zhu was the Chief Medical Officer at Maxinovel Pharmaceuticals. His career in the United States includes stints at Roche, Genentech, and Takeda, where he held positions with increasing responsibilities, including biomarker & experimental medicine leader, senior clinical scientist, and senior medical director. Prior to his development experience, he was a biotech scientist working on translational biology and preclinical research at Sunesis and Osel in the San Francisco Bay Area. After coming to China in 2017, Dr. Zhu first worked at Shanghai Henlius, building up a clinical development group and overseeing the development of multiple biosimilars and innovative drugs in oncology and immunology. Then he joined Roche Pharma-Shanghai Innovation Center as a global program

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& medical dual leader in early-stage clinical research in immunology and infectious diseases, leading the overall development of several new molecules and international multi-center clinical trials. Dr. Zhu graduated from Nanjing University Medical School through China’s first seven-year medical program. After practicing medicine shortly, he studied at the University of Rochester School of Medicine and Dentistry, and received a Ph.D. in Microbiology and Immunology. Later he completed industrial postdoctoral training in discovery research at the immunology company DNAX Research Inc (now part of Merck).

Dr. Xinyi Gu, our chief financial officer, with a strong scientific background, equity research expertise across multiple therapeutic areas and treatment modalities and long-standing ties to capital markets, has over 17 years of biopharmaceutical industry experience across management consulting, healthcare research, and public market investment. Before joining us, Dr. Gu was a Senior Analyst at Millennium Management, overseeing investments in global pharmaceutical and biotechnology companies. Prior to that, he was a Vice President and Global Pharmaceutical Equity Research Analyst at Jefferies LLC, where he covered global large-cap pharmaceutical companies across multiple therapeutic areas, evaluated companies for initial and secondary public offerings, and helped to author multiple pharmaceutical industry and therapeutic deep dives. Prior to Jefferies, Dr. Gu was a management consultant at McKinsey & Company and also held equity research positions at Wells Fargo Securities. Dr. Gu holds a Ph.D. in Pharmaceutical Sciences from the University of Michigan and graduated *summa cum laude* with a Bachelor of Science degree in Biochemistry from the University of Illinois at Urbana-Champaign.

We are further strengthened by a distinguished consortium of blue-chip institutional investors spanning state-owned investment institutions, healthcare-focused strategic partners, global funds, and top-tier market-driven financiers. Key investors include, among others, Decheng, SDIC, Sherpa, Hony Capital, as well as global funds Mirae Asset Management, Cormorant, and Octagon. Through successive financing rounds, we have secured strategic capital, underscoring profound market conviction in our antibody drug innovation platform. This multi-dimensional alliance unlocks unparalleled access to therapeutic ecosystems, cross-border operational expertise, and capital market intelligence, accelerating our global mission to deliver breakthrough antibody therapies.

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OUR STRATEGIES

Rapidly Advance the Clinical Development of Our Clinical Drug Candidates Towards Commercialization

We have formulated and are implementing a stepwise clinical development strategy that would allow us to thoroughly evaluate the therapeutic potential of our drug candidates. Leveraging the expertise of our clinical development team and execution capabilities, we are strategically advancing the clinical development of our drug candidates. By optimizing resource allocation and aligning with global regulatory frameworks, we aim to expedite approvals for high-value therapeutics that address unmet medical needs. Our clinical development plans for our programs are as follows:

- ***EMB-01 (EGFR/cMET)***: Upon completion of Phase I portion of the first-in-human Phase I/II trial of EMB-01 for advanced/metastatic solid tumors (predominantly enrolling NSCLC patients) in September 2021, we initiated a Phase Ib/II trial to evaluate EMB-01 monotherapy in gastrointestinal cancers, including gastric, hepatocellular, biliary tract and colorectal cancer, in October and December 2021 in the United States and China, respectively. In this trial, EMB-01 monotherapy demonstrated encouraging efficacy signals and manageable safety in heavily treated mCRC patients. Based on encouraging interim trial results, we submitted an IND application for a Phase II trial of EMB-01 monotherapy in the third-line mCRC to the NMPA in March 2025 and received the IND approval in May 2025. We expect to initiate this Phase II clinical trial around year end of 2025.
- ***EMB-01 in combination with chemotherapy***: As a combination strategy, we are also planning a Phase Ib study of EMB-01 in combination with chemotherapies in multiple line settings. We have obtained IND approval for EMB-01 in combination with a chemotherapy regimen from the NMPA in January 2024. We expect to initiate this trial following the interim data readout from the planned Phase II clinical trial of EMB-01 monotherapy in mCRC patients in China.
- ***EMB-07 (ROR1/CD3)***: As of the Latest Practicable Date, EMB-07 was being investigated in a Phase I, open-label study in patients with advanced solid tumors or lymphomas, aiming to evaluate safety and tolerability of intravenous EMB-07 and to determine the maximum tolerated dose and/or recommended Phase II doses. The study is currently ongoing in China and Australia. We have received IND approval from the FDA in April 2025 for this Phase I trial. We expect to complete the trial in the first quarter of 2026. Following the completion of this trial, we anticipate initiating a Phase II study of EMB-07 monotherapy. Additionally, we are planning clinical trials of EMB-07 in combination therapy with standard of care regimens for the treatment of diffuse large B-cell lymphoma (“DLBCL”). We obtained IND approval from the NMPA in September 2025 for this Phase I clinical trial of EMB-07 in combination therapy. We expect to initiate this trial in the second quarter of 2026.

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- **EMB-06 (BCMA/CD3):** The first-in-human study of EMB-06 in R/R MM has shown a wide therapeutic window with strong efficacy at the highest doses, a low cytokine release syndrome incidence and no ICANS, indicative of potentially favorable profiles for autoimmune disease. We intend to develop EMB-06/CND106 in autoantibody-related diseases/indications in China (including Hong Kong, Macau and Taiwan).
- **EM1032 (ALPP(G)/CD3):** We expect to submit an IND application for EM1032 for the treatment of solid tumors in the first quarter of 2026, and further seek collaboration opportunities with global pharmaceutical companies.
- **EM1034 (LY6G6D/CD3):** We expect to submit an IND application for EM1034 with the NMPA for the treatment of solid tumors in the fourth quarter of 2026, and further seek collaboration opportunities with global pharmaceutical companies.

Advance and Expand Our Pipeline Through Optimizing Our R&D Platform

Leveraging our systematic R&D framework, we have advanced numerous drug candidates into clinical development. Our proprietary technology toolbox of bispecific formats and CD3 binder panel has been instrumental in this progress, enabling us to create bispecific antibodies with high specificity, affinity, and optimal therapeutic properties. Moving forward, we will focus on accelerating the clinical progress of existing pipeline assets while aligning R&D timelines with commercialization milestones, thereby establishing a solid foundation for our Company’s long-term growth.

Our therapeutic strategy is centered on expanding R&D efforts into high-impact areas with medical needs, particularly solid tumors and autoimmune diseases. This targeted approach enables us to build on our technological strengths and pursue the development of new therapeutic options. Building upon clinically proven bispecific formats and TCE technology, our future innovation focuses on three key areas:

- **Tri-specific engager technology for next-generation B cell depletion:** B cell development is a complex process involving various stages and subtypes of B cell lineages. Common B cell antigens such as CD19, CD20, and BCMA are expressed only on certain B cell subsets, not on all B cells. Targeting multiple B cell antigens with a dual-target TCE can be an effective next-generation strategy to achieve more complete B cell depletion and enhance efficacy. Our EM1039 embodies this concept by targeting a novel combination of two B cell targets, resulting in deep depletion of tissue B cells, plasma cells, and plasma blasts.

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- ***Novel immune cell engagers for autoimmune indications.*** While current treatments for autoimmune diseases focus on depleting B cells, other immune cells such as subsets of T cells, eosinophils, and inflammatory cells also play a role in mediating autoimmunity. Specific depletion of these cells can potentially provide significant therapeutic benefits to patients across various autoimmune indications.
- ***proTCEs with masking technology for solid tumor indications.*** Many tumor-associated antigens are expressed at high levels on tumor cells but also on normal, healthy cells, making them challenging targets for TCEs. Developing proTCEs with masking technology can reduce toxicity in normal tissues through conditional activation of TCEs only at the tumor site, and significantly improve the therapeutic window. We believe this approach represents the future trend for solid tumor TCEs and we aim to develop and optimize our proprietary proTCE technologies.

Strengthen Global Collaboration Ecosystem to Add Pipeline Value

To maximize the value of our pipeline and fully leverage multinational pharmaceutical resources, we employ flexible business models to collaborate with leading global partners such as Almirall and Candid. These partnerships are designed to expand our global footprint and exploit the potential of our proprietary technology platforms and pipeline assets. Our partners have the bandwidth to develop and commercialize assets which are outside our focused areas or help us to advance programs globally by adding resources and expertise. With the revenue from these collaborations, we can also support further development of our assets and platforms.

As we continue to expand our business globally, we will further broaden the applications of our platform technologies. By leveraging advanced technological platforms, we aim to maintain close partnerships with global collaborators to co-develop clinically valuable product pipelines, explore commercialization opportunities in domestic and international markets, and develop new therapies to enrich our R&D pipeline. By building on our expertise in TCE development, we plan to extend our therapeutic focus to solid tumors, hematologic malignancies, and autoimmune diseases, addressing critical medical needs. This strategy will be supported by ongoing platform improvements and cross-functional collaboration to advance our pipeline and expand potential patient impact.

Strategically Enhance Our Operation Capabilities for Commercial Launch

Upon regulatory approvals of our drug candidates, we plan to adopt an asset-light strategy to advance our manufacturing and commercialization goals, ensuring economic viability and operational efficiency. In the short term, we will focus on strategic collaborations with industry-leading enterprises to leverage their well-developed sales channels and expansive marketing networks. We believe this approach will facilitate cost-effective and efficient market entry both domestically and internationally. As our products progress and our market presence strengthens, we then plan to establish an in-house sales team with specialized expertise in key therapeutic areas. By fostering synergistic partnerships, we aim to enhance market penetration in core regions, combining our strengths with those of our collaborators to maximize impact

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and reach. For our operational capabilities in production, we plan to collaborate with international and/or local CDMOs. This approach is designed to optimize cost control while mitigating geographic risks, ensuring a robust and resilient production strategy that supports our long-term growth.

As our product pipeline grows and approaches commercialization, we are executing a multifaceted strategy to boost operational efficiency. By tightly integrating R&D with commercialization efforts, we plan to streamline supply chains and forge strategic CDMO collaborations to accelerate progress. We are adopting lean workforce management practices, strategically deploying talent and leveraging digital tools while maintaining a compact yet highly specialized team structure that balances sustainable growth with fiscal responsibility. These coordinated initiatives create an integrated ecosystem that expedites the translation of research into market value.

Further Attract, Train and Retain Talent to Sustain and Expand Our Capabilities

We are actively expanding our talent pipeline by recruiting and retaining elite professionals in drug R&D, clinical development, and commercialization, which is critical to scaling our capabilities amid rapid growth. In the short term, we will expand our discovery and clinical team in immunology, with a focus on autoimmune discovery and clinical development. In the long term, we will continue to expand in the following areas: (i) biological engineering to support increasingly complex molecular constructions, including trispecifics and proTCEs; (ii) translational research for autoimmune and oncology TCE development; (iii) CMC, including project management and quality assurance scientist; and (iv) medical director for late-stage projects. By executing global clinical development strategies with speed and efficiency, we accelerate the advancement of new therapies. Building this foundation of world-class talent and agile execution will propel us toward becoming a leading global biopharmaceutical company, ensuring sustained innovation for the long term.

OUR DRUG CANDIDATES

Since inception, we have discovered and developed multiple clinical-stage assets and built a rich preclinical pipeline in-house. Our pipeline comprises three clinical-stage drug candidates, including our Core Product EMB-01 (targeting EGFR/cMET) and two TCE-based key products EMB-06 (targeting BCMA/CD3) and EMB-07 (targeting ROR1/CD3), and four preclinical drug candidates, EM1032 (targeting ALPP(G)/CD3), EM1034 (targeting LY6G6D/CD3), EM1039 and EM1042. With a deep understanding of underlying disease mechanisms, particularly T cell-mediated immunity, and extensive expertise in antibody engineering, we aim to develop next-generation bispecific antibody and T-cell engaging therapeutics that either address novel targets or possess superior profiles.

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The following chart summarizes the development status of our selected drug candidates as of the Latest Practicable Date:

Program ⁽⁶⁾	Target	Indication	Line(s) of treatment	Mono/Combo	PCC	IND-enabling	Phase I	Phase II	Phase III	Key Regulatory Authorities	Current Status/Upcoming Milestone	Rights	Partners
		Advanced/metastatic GI Cancers (CRC, HCC, gastric, biliary tract cancer)	≥3L	Mono						FDA, NMPA	Completed patient's enrollment in March 2025/Expected Phase III trial completion in Q4 2025	Global	/
★ EMB-01	EGFR/GMET	mCRC	≥3L	Mono						NMPA	IND approval from the NMPA in May 2025/Expected Phase II initiation around year end of 2025 ⁽⁶⁾	Global	/
		mCRC	2L, 3L	+Chemo						NMPA	IND approval from the NMPA in January 2024/Expected Phase I initiation pending interim data readout of Phase II mono	Global	/
★ EMB-07	ROR1/CD3	Solid tumors/relapsed or refractory lymphoma	≥3L/≥2L ⁽⁵⁾	Mono						NMPA	Dose-escalation still ongoing/Expected Phase I trial completion in Q1 2026	Global	/
		DLBCL	1L, 2L	Combo ⁽⁶⁾						NMPA	IND approval in September 2025/Expected study initiation in Q2 2026	Global	/
EMI1032	ALPP(G)/CD3	Solid tumors	/	TBD						/	Expected IND submission in Q1 2026	Global	/
EMI1034	LY6G6D/CD3	Solid tumors	/	TBD						/	Expected IND submission in Q4 2026	Global	/
★ EMB-06 ⁽⁵⁾	BCMA/CD3	SLE, gMG	Relapsed/Refractory	Mono						NMPA	Ongoing Phase I trials in SLE and gMG sponsored by Candig ⁽⁵⁾	China ⁽⁵⁾	Candid
		TED	/	Mono						NMPA	Ongoing Phase I trial in TED sponsored by Candig ⁽⁵⁾	China ⁽⁵⁾	Candid
EMI1039	Undisclosed trispecific TCE	Autoimmune diseases (B cell related)	/	TBD						/	Expected initiation of IND-enabling studies by Q2 2026	Global	/
EMI1042	Undisclosed TCE	Autoimmune diseases (Inflammatory cell related)	/	TBD						/	Expected initiation of IND-enabling studies by Q2 2026	Global	/

 TCE Programs
 Non-TCE Programs
 Core Product
 Key Product

Abbreviations: 1L = First-line, 2L = Second-line, 3L = Third-line, Chemo = Chemotherapy, Combo = Combination Therapy, CRC = Colorectal Cancer, FDA = U.S. Food and Drug Administration, GI = Gastrointestinal Cancer, gMG = Generalized Myasthenia Gravis, H1 = First Half, H2 = Second Half, HCC = Hepatocellular Carcinoma, IND = Investigational New Drug, mCRC = metastatic colorectal cancer, Mono = Monotherapy, NA = Not Applicable, NMPA = National Medical Products Administration of the PRC, PCC = Pre-clinical Candidate Compound, Q1 = First Quarter, Q4 = Fourth Quarter, SLE = Systemic Lupus Erythematosus, TBD = To Be Determined, TCE = T-cell Engager, TED = Thyroid Eye Disease.

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Notes:

- (1) All of our drug candidates are developed in-house.
For each drug candidate, our clinical development typically begins with a dose escalation trial to characterize safety, tolerability, and pharmacokinetics and to identify a recommended dose or dose range, where multiple patient groups across different tumor types or indications are enrolled to assess both safety and efficacy of the drug candidate. Where scientifically justified and permitted by protocol and ethics approvals, we may include expansion cohorts that enroll patients with predefined tumor types or biomarker-defined subpopulations to obtain preliminary signals of activity and to refine the target population. Advancement to later-stage development for any indication is not automatic and is contingent on prespecified, candidate-specific criteria (e.g., acceptable safety profile, exposure consistent with target engagement, and clinically meaningful antitumor activity per RECIST or indication-appropriate criteria), as well as on the availability of validated patient selection strategies. In addition, progression is subject to the requirements of Competent Authorities, including protocol amendments, alignment on the recommended Phase 2 dose, acceptance of the proposed indication and endpoints, and, where applicable, fulfillment of CMC, nonclinical, and safety monitoring conditions. Based on the results from this trial, we determine which indications to prioritize for advancement into later-stage clinical development.
- (2) We granted Candid an exclusive, royalty-bearing and sublicensable license under our applicable controlled patents and know-how to research, develop, manufacture and commercialize EMB-06 for the diagnosis, treatment or prevention of all human and non-human diseases outside China (including Hong Kong, Macau and Taiwan) (the “Candid Territory”). We retain the right to research, develop, manufacture and commercialize EMB-06 for the diagnosis, treatment or prevention of all human and non-human diseases in China (including Hong Kong, Macau and Taiwan) (the “EpimAb Territory”).
Under the EMB-06 License and Collaboration Agreement, we agreed to wind down our ongoing multi-center Phase I/II clinical trial of EMB-06 for oncology indications according to a wind-down plan. The wind-down plan involves wrapping up the Phase I dose-escalation portion of the Phase I/II clinical trial of EMB-06 for relapsed or refractory multiple myeloma, not pursuing Phase II dose-expansion portion, and notifying trial sites in China and Australia of the study closure. The rationale for this wind-down is to avoid any potential impact of the ongoing oncology trial in China on Candid’s conduct of clinical trials of EMB-06 in autoimmune indications and its future regulatory submissions in the Candid Territory. Following the wind-down, we will not develop or license EMB-06 in the EpimAb Territory until Candid initiates a pivotal clinical trial of EMB-06. Upon Candid’s initiation of a pivotal clinical trial of EMB-06, we will initiate pivotal trial in China by either running an independent pivotal trial or joining a global pivotal trial of Candid by adding patients from China in antibody-related autoimmune diseases/indications — diseases in which pathogenic autoantibodies produced by the patient’s immune system directly drive tissue damage or pathophysiological changes. We currently do not expect to pursue further development of EMB-06 in China in oncology in the near term.
The EMB-06 License and Collaboration Agreement provides that, upon Candid’s initiation of a pivotal clinical trial of EMB-06, we may initiate studies for our own regulatory submissions in the EpimAb Territory and are responsible for them at our own expense. Candid is responsible for the development of EMB-06 in the Candid Territory at its own expense. Nonetheless, in order to accelerate early clinical development of EMB-06 worldwide, Candid may, although it does not have any commercialization rights in China, conduct clinical trials in the EpimAb Territory for the purposes of obtaining regulatory approval in the Candid Territory. Therefore, to expedite worldwide development of EMB-06 and in compliance with the EMB-06 License and Collaboration Agreement, Candid is conducting clinical trials of EMB-06 for systemic lupus erythematosus (SLE), generalized myasthenia gravis (gMG) and thyroid eye disease (TED) in China, as well as multiple investigator-initiated studies. We will have access to all data generated by Candid. We may use such obtained data to support our own regulatory submissions in the EpimAb Territory. This arrangement allows us to leverage global development efforts while ensuring that our development and regulatory activities in China remain under our control and consistent with our contractual rights. For clarification, we will be the named marketing authorization holder of the regulatory approvals of EMB-06 in the EpimAb Territory. See “Business — Our Drug Candidates — Our Clinical-Stage Drug Candidates — EMB-06 (BCMA/CD3), Our Key Product — Clinical Development Plan” for details.
- (3) Including Hong Kong, Macau and Taiwan.

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- (4) Upon completion of Phase I portion of a first-in-human Phase I/II trial of EMB-01 for advanced/metastatic solid tumors in September 2021, we initiated a Phase Ib/II trial to evaluate EMB-01 monotherapy in gastrointestinal cancers, including gastric, hepatocellular, biliary tract and colorectal cancer, in October and December 2021 in the United States and China, respectively. In this trial, EMB-01 monotherapy demonstrated efficacy signals and manageable safety in heavily treated mCRC patients. Based on encouraging interim trial results, we submitted an IND application for a Phase II trial of EMB-01 monotherapy in the third-line mCRC with the NMPA in March 2025 and received the IND approval in May 2025. We expect to initiate this Phase II clinical trial around year end of 2025.
- (5) In the Phase I clinical trial of EMB-07 monotherapy for solid tumors and relapsed/refractory lymphomas, patients in the solid tumor cohort were generally enrolled at later lines of therapy following exhaustion of standard treatment options; patients in the relapsed/refractory lymphoma cohort generally had ≥ 2 or ≥ 3 prior lines of treatment.
- (6) EMB-07 is currently being evaluated in a platform trial across multiple combination regimens, including (i) EMB-07 with R-CHOP (rituximab, cyclophosphamide, vincristine, doxorubicin, and prednisone) as a first-line treatment, as well as several second-line regimens including (ii) EMB-07 with R-GemOx (rituximab, gemcitabine, and oxaliplatin), (iii) EMB-07 with rituximab and polatuzumab (chemo-free), (iv) EMB-07 with rituximab, lenalidomide, and zanubrutinib (chemo-free), and (v) EMB-07 with rituximab and tucidimostat.

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Our Clinical-Stage Drug Candidates

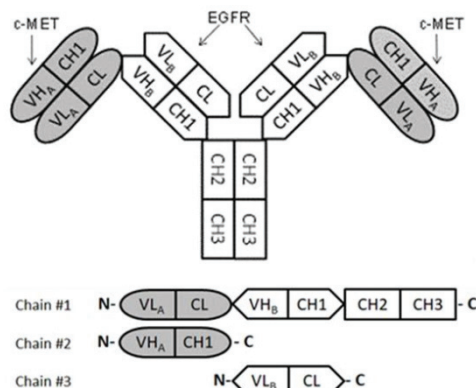
EMB-01 (EGFR/cMET), Our Core Product

EMB-01 is a tetravalent bispecific antibody that simultaneously targets EGFR and cMET, designed to inhibit cell proliferation and block signaling crosstalk between these receptors. EMB-01 is designed based on our FIT-Ig platform, where the binding domains are connected in a crisscross orientation without peptide linkers or artificial mutations, and allows for simultaneous high-affinity tetravalent binding to both EGFR and cMET. Unlike conventional bispecific formats adopted by other EGFR/cMET bispecific antibodies, the structure of EMB-01 is capable of inducing more rapid and efficient co-degradation of both receptors, achieving a level of degradation that surpasses other bivalent bispecific formats, monoclonal antibodies alone or in combination therapies. EMB-01 is currently under clinical evaluation for the treatment of mCRC.

We completed a first-in-human Phase I/II trial of EMB-01 for advanced/metastatic solid tumors (primarily enrolling NSCLC patients) in July 2023. In December 2021, we obtained an IND approval from the NMPA for the Phase Ib/II clinical trial of EMB-01 for advanced/metastatic gastrointestinal cancers (in four indications including mCRC), with FDA approval obtained in October 2021 and subsequently initiated the Phase Ib/II trial. As of December 4, 2024, we have enrolled 52 patients in this Phase Ib/II trial, including 48 mCRC patients, and we expect to complete the trial in the fourth quarter of 2025. Additionally, we submitted an IND application to the NMPA in March 2025 for a Phase II trial evaluating EMB-01 monotherapy focused on mCRC and received the IND approval in May 2025. We expect to initiate this Phase II clinical trial around the year end of 2025. Furthermore, in January 2024, we initiated a combination therapy strategy following IND approval by the NMPA. This approval enables the Phase Ib study of EMB-01 in combination with chemotherapies in mCRC. We expect to initiate this trial after obtaining preliminary readouts from the Phase II EMB-01 monotherapy study in mCRC.

Drug Design and Mechanism of Action

The molecular structure of EMB-01 is illustrated below:



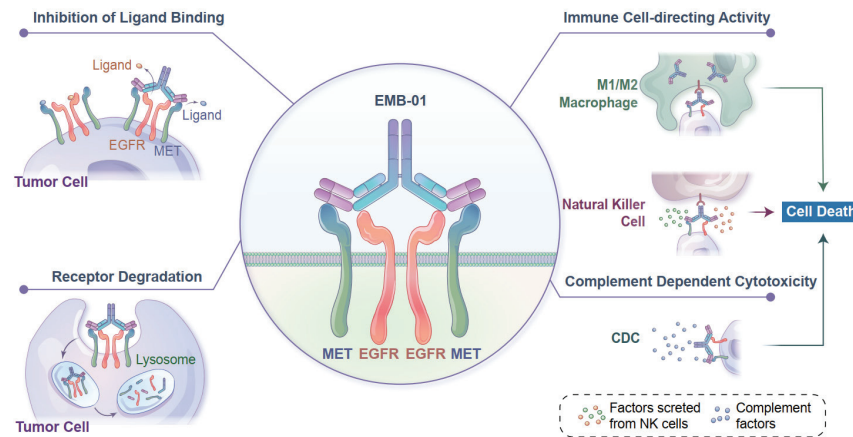
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EMB-01 is a bispecific antibody engineered to simultaneously target EGFR and cMET, two receptor tyrosine kinases implicated in tumor proliferation, survival, and resistance. EMB-01 forms a unique tetravalent structure by directly fusing anti-EGFR and anti-cMET Fab domains in a crisscross orientation. This format can enhance avidity and ensure robust engagement with EGFR and cMET receptors, effectively overcoming tumor heterogeneity and addressing resistance mechanisms like EGFR mutations and crosstalk with cMET. By simultaneously binding to both EGFR and cMET, EMB-01 effectively blocks the interaction of their respective ligands, thereby inhibiting the downstream activation of oncogenic signaling pathways. In contrast to monospecific antibodies or combination therapies, EMB-01 induces the internalization and co-degradation of both receptors, which represents a critical mechanism for overcoming resistance mechanisms such as compensatory pathway activation or acquired gene mutations. This dual degradation strategy demonstrates particular efficacy in tumors harboring acquired EGFR or cMET signal transduction, conditions that frequently contribute to resistance against approved therapies. The fully human sequences and wild-type IgG1 Fc domain of EMB-01 ensure minimal immunogenicity while preserving native Fc effector functions. Such design principle is corroborated by Phase I clinical data: among 107 patients with evaluable baseline and post-dose ADA results, 4 patients (3.7%) who were ADA negative at baseline developed treatment-emergent ADAs. In addition, 12 patients were ADA positive at baseline, of whom 5 had at least one post-baseline positive ADA result without any increase (≥ 1 fold) in ADA titer after treatment.

Beyond direct receptor inhibition, EMB-01 induces antibody-dependent cellular cytotoxicity against tumor cells by engaging immune effector cells via its Fc region, including natural killer (NK) cells and macrophages. Furthermore, EMB-01 triggers complement-dependent cytotoxicity, resulting in the formation of membrane attack complexes that directly lyse tumor cells. These immune-mediated mechanisms synergistically interact with its receptor-blocking capabilities to enhance antitumor efficacy, particularly in EGFR-driven cancers where immune evasion is prevalent. Preclinical studies further demonstrate that the tetravalent binding of EMB-01 facilitates receptor internalization and degradation, which represents a critical mechanism for overcoming drug resistance in tumors harboring acquired EGFR or cMET mutations. Data from a Phase Ib/II study for EMB-01 in CRC patients presented at the 2025 AACR annual meeting demonstrated EMB-01’s potential to transform the future CRC treatment landscape.

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The following diagram illustrates the mechanism of action of EMB-01:



Source: Company data

Market Opportunities and Competition

We are actively pursuing a comprehensive clinical development plan of EMB-01 with a strategic focus on mCRC. CRC, encompassing colon and rectal cancer, is one of the most prevalent malignancies worldwide, developing from the colon or rectum. It often begins as polyps, abnormal growths in the intestinal lining that can become cancerous if untreated. Adenocarcinomas account for 95% of CRC cases, originating in mucus-producing cells of the colon and rectum. Other rare types include gastrointestinal stromal tumors, sarcomas, and lymphomas, which have distinct cellular origins. In China, the number of new CRC cases increased to 542.4 thousand in 2024 at a CAGR of 2.6% and is projected to reach 653.3 thousand by 2034 at a CAGR of 1.9% from 2024 to 2034. Globally, the incidence of CRC grew at a CAGR of 1.6% from 1,880.7 thousand in 2020 to 2,005.2 thousand in 2024, expected to reach 2,527.1 thousand by 2034 at a CAGR of 2.3% from 2024 to 2034.

Current therapies for CRC face several limitations, primarily due to the necessity of tailoring treatment based on specific genetic mutations. For instance, tumors harboring RAS mutations (e.g., KRAS, NRAS) can demonstrate resistance to EGFR inhibitors such as cetuximab and panitumumab. Additionally, RAF mutations (e.g., BRAF V600E), characterized by aggressive progression and poor prognosis, often require combination approaches involving BRAF and MEK inhibitors. Furthermore, microsatellite instability-high (MSI-H) mutations respond well to immune checkpoint inhibitors, but their efficacy can be limited in microsatellite stable (MSS) population, which comprises the majority of cases. These molecular distinctions underscore the challenge of treatment selection, as the heterogeneous nature of CRC demands precision medicine approaches that integrate targeted therapies while addressing resistance mechanisms and optimizing therapeutic durability.

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The following table summarizes the information of approved antibody drugs for the treatment of CRC in China:

Drug Name	Brand Name	Target	Company	Indication	Mono/combo	Approval Date
Ipilimumab	逸沃 YERVOY	CTLA4	Bristol Myers Squibb	CRC	Combo	2024-10-09
Bevacizumab	安维汀 Avastin	VEGF	Roche	CRC	Combo	2010-02-26
Cetuximab	爱必妥 Cetuximab	EGFR	Merck	CRC	Combo	2005-12-30

Source: NMPA, Frost & Sullivan

EGFR and cMET represent highly promising targets in the development of bispecific antibody therapies, particularly for gastrointestinal cancers and CRC, where dysregulated signaling involving these pathways plays a central role in tumor progression and therapeutic resistance. EGFR activation, through ligand binding or mutations, promotes tumor growth by driving downstream MAPK and PI3K/AKT pathways, while cMET activation, often via HGF-dependent mechanisms or gene amplification, further enhances these oncogenic signals. These pathways not only independently contribute to tumor proliferation and invasion but also exhibit significant crosstalk, with compensatory activation of one often occurring when the other is inhibited. This compensatory nature is especially pronounced in gastrointestinal cancers, including CRC, where monotherapy targeting either EGFR or cMET frequently results in therapeutic resistance. Bispecific antibodies that simultaneously inhibit both EGFR and cMET provide a more comprehensive blockade of these key pathways, preventing receptor phosphorylation and downstream signaling while effectively suppressing tumor cell proliferation and overcoming resistance mechanisms in advanced or refractory disease.

Beyond tumor cell-intrinsic pathways, EGFR and cMET signaling also contribute significantly to shaping the tumor microenvironment, which is a critical consideration in gastrointestinal cancers and mCRC. These pathways promote angiogenesis, immune suppression, and stromal remodeling, creating a tumor microenvironment that fosters tumor progression and resistance to conventional therapies. By targeting both EGFR and cMET, bispecific antibodies can block redundant and compensatory signaling pathways that tumors exploit for survival, providing a more robust and durable treatment option for CRC patients, particularly those with advanced or treatment-resistant disease. The ability of bispecific antibodies to address both tumor-intrinsic and tumor-extrinsic mechanisms offers a transformative therapeutic strategy to improve outcomes in patients with these aggressive malignancies. As of the Latest Practicable Date, amivantamab, developed by Janssen, is the first EGFR/cMET bispecific antibody marketed globally, having received approval for the treatment of NSCLC, and is currently leading in Phase III clinical development for CRC. Our EMB-01, leveraging its unique tetravalent structure, demonstrated an outstanding safety and efficacy profile in the Phase Ib/II trial, being among the earliest EGFR/cMET bispecific antibodies to enter Phase II clinical trial for the treatment of CRC. As of the Latest Practicable Date, there was no approved EGFR/cMET bispecific antibody for the treatment of CRC globally.

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The following table summarizes the information of clinical-stage EGFR/cMET antibody drugs for the treatment of CRC globally and in China as of the Latest Practicable Date:

Global and China Pipelines								
Product	Company	Target	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-01	Our Company	EGFR/ cMET	CRC	II	Mono	Third-line	2025/11/05	China
Amivantamab	Janssen	EGFR/ cMET	Solid tumors (including CRC)	III	Combo	First-line	2022/05/11	US, China, etc.
TQB2922	ChiaTai Tianqing	EGFR/ cMET	CRC	I/II	Combo	Third-line/ Last-line	2025/06/17	China
MCLA-129	Betta Pharmaceuticals	EGFR/ cMET	Solid tumors (including CRC)	I/II	Mono/Combo	Second line/ Third-line	2021/05/13	China
HS-20117	Hansoh Biopharmaceutical	EGFR/ cMET	Solid tumors, (including CRC)	I	Combo	Second-line/ Third-line/ Last-line	2025/04/16	China
FPI-2053	Fusion Pharmaceuticals	EGFR/ cMET	Solid tumors, (including CRC)	I	Combo	Second-line	2023/11/27	US, Canada

Source: *Clinical Trials, Frost & Sullivan*

Competitive Advantages

Balanced inhibition of both EGFR and cMET targets

The parental anti-EGFR and anti-cMET monoclonal antibodies selected for EMB-01 construction are both high-affinity monoclonal antibodies with comparable ligand/receptor blocking activity against EGFR and cMET. The balanced inhibition strategy employed by EMB-01 addresses both cellular subsets, offering enhanced efficacy against tumor cells that depend on the synergistic interactions between the EGFR and c-MET pathways. This dual-targeted approach can potentially enable more effective elimination of heterogeneous tumor cell populations compared to single-target prioritized blocking mechanisms. In contrast, certain bispecific antibodies with the same targets, such as amivantamab, adopt an unbalanced design in which a higher-blocking anti-cMET monoclonal antibody is paired with a relatively low-affinity anti-EGFR parental monoclonal antibody. These bispecific antibodies with a priority over single-target inhibition may trigger compensatory pathway activation, leading to drug resistance, and their therapeutic utility is often restricted to c-MET dependent tumors with attenuated efficacy against EGFR-driven malignancies. By addressing these limitations, EMB-01’s balanced inhibition strategy may be beneficial in treating tumors where signaling from either or both EGFR/cMET receptors drives tumor growth and proliferation, as well as potential resistance pathways. Additionally, EMB-01 also induces co-degradation of both EGFR and cMET, a feature that is less pronounced in other EGFR/cMET bispecific antibodies.

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This receptor co-degradation suppresses downstream oncogenic signaling cascades by removing the initiating receptors, thereby enhancing antitumor activity. Collectively, these properties suggest that EMB-01 may have wider applicability in drug-resistant settings and the potential to expand the therapeutic window in challenging clinical scenarios.

Our dual-targeted design for EMB-01 was informed by scientific evidence that both EGFR and cMET signaling pathways are critically involved in the pathogenesis and progression of CRC. In CRC, EGFR signaling is a major disease driver, while cMET is also highly expressed, suggesting that simultaneous targeting may address tumor heterogeneity and overcome resistance mechanisms associated with single-target therapies. Recent innovations in single-target biologics for CRC, such as ADCs and small molecules, typically require strict biomarker selection and may only benefit a limited patient population. In contrast, our dual-targeted approach has the potential to benefit a broader range of patients, similar to anti-EGFR monoclonal antibodies, and can be readily combined with established therapies such as chemotherapy or anti-VEGF agents.

Notably, head-to-head preclinical studies have demonstrated that EMB-01’s design translates into comparably effective suppression of downstream EGFR and cMET signaling and potent anti-tumor efficacy. In CRC-derived organoid models, EMB-01 showed greater anti-tumor activity than cetuximab developed by BMS (anti-EGFR mAb). In lung cancer CDX models, EMB-01 demonstrated superior efficacy compared to amivantamab developed by Janssen (EGFR/cMET BsAbs). In lung cancer PDX models, EMB-01 outperformed staurosporine (pan-kinase inhibitor, comparator: staurosporine). Furthermore, in the lung cancer PDX model, EMB-01 exhibited significant and durable tumor suppression relative to the EGFR tyrosine kinase inhibitor AZD9291 developed by AstraZeneca. Although the foregoing comparative results were generated in preclinical studies and may not be predictive of the results of later-stage clinical trials, we believe meaningful insights could be drawn that EMB-01’s dual-targeted mechanism can lead to more effective elimination of heterogeneous tumor cell populations, supporting the rationale for its differentiated clinical development.

Potent *in vitro* and *in vivo* efficacy

EMB-01 demonstrates a unique dual-targeting “2+2” structural format, enabling simultaneous engagement of EGFR and cMET with binding affinity comparable to in-house monoclonal antibodies derived from panitumumab (Vectibix[®]) sequences. Beyond conventional mechanisms like antibody-dependent cellular cytotoxicity, complement-dependent cytotoxicity, and receptor inhibition, EMB-01 uniquely induces co-degradation of both EGFR and cMET, a mechanism that may circumvent cross-resistance observed in tumors reliant on either pathway, offering a potential solution to acquired resistance in EGFR- or cMET-driven cancers. On NCI-H292 and NCI-H1975 cell surfaces, EMB-01 drives receptor endocytosis and degradation, effectively suppressing downstream signaling. Notably, it outperforms individual anti-EGFR or anti-cMET monoclonal antibodies, suggesting synergistic disruption of compensatory pathways often implicated in tumor survival. Furthermore, EMB-01 synergizes with osimertinib in osimertinib-insensitive cell lines, highlighting its potential to resensitize tumors to third-generation EGFR TKIs, a critical advantage in

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refractory NSCLC. *In vivo*, EMB-01 exhibits superior and more durable antitumor activity than anti-EGFR monoclonal antibody monotherapy across multiple models, attributable to its dual-pathway blockade mechanism. Together, these properties position EMB-01 as a therapeutic candidate for tumors dependent on EGFR/cMET signaling.

Encouraging efficacy signals in late-line mCRC patients

In the Phase Ib/II study, EMB-01 demonstrated encouraging therapeutic potential for heavily pretreated mCRC patients. Among left-sided, RAS/RAF wild-type mCRC patients who received a median of three prior therapies (range: 1-7), EMB-01 demonstrated an ORR of 24%, representing that nearly one quarter of patients experienced measurable tumor shrinkage, translating to direct symptom relief and potential quality-of-life improvements for these advanced cancer patients. A DCR of 83% was also observed, indicating the majority of patients achieved either tumor regression or stable disease, which clinically represents delayed disease progression and extended time before needing additional therapies.

Particularly noteworthy are the outcomes in patients who had failed prior anti-EGFR treatment, where EMB-01 still produced an ORR of 22% and DCR of 78%. For these patients who typically have few remaining options, these response rates could mean additional months of disease control and maintained functional status. These promising results position EMB-01 as a potential therapeutic breakthrough for late-line mCRC management, particularly for patients failing prior EGFR-targeted regimens.

Summary of Clinical Trial Results

Completed Phase I/II clinical trial of EMB-01 in patients with advanced/metastatic solid tumors

We launched the Phase I/II trial of EMB-01 in patients with advanced/metastatic solid tumors in December 2018 in China and the United States, completed the Phase I of this trial in September 2021 and initiated the Phase II in the same month. We completed this trial in July 2023. We were the sponsor of this clinical trial.

Trial design. This trial is a first-in-human, multicenter, open-label, multiple-ascending dose Phase I/II study in patients with advanced/metastatic solid tumors who had progressed on available standard therapies or for which no standard therapy existed. It consists of Phase I (dose escalation) in patients with advanced/metastatic solid tumors to evaluate the safety and tolerability of EMB-01 when administered intravenously and determine its maximum tolerated dose (“**MTD**”) and/or recommended Phase II dose (“**RP2D**”), and Phase II (dose expansion) in patients with advanced/metastatic NSCLC to estimate preliminary antitumor activity of EMB-01 at RP2D(s) and continue to evaluate its safety and tolerability. The study consisted of a molecular prescreening period (Phase II only), clinical screening period (-28 to -1 days), treatment cycles (each cycle was 28 days; the maximum treatment duration was up to 2 years, i.e., 96 weeks), and follow-up period (30 days after the last dose safety and disease progression follow up).

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This study aims to evaluate the safety and tolerability, characterize PKs and estimate preliminary antitumor activity of EMB-01. The Phase I trial followed a standard “3 + 3” cohort design for dose escalation which was considered adequate and well-accepted by relevant authorities. The rationale for the proposed Phase I starting dose was based on the evaluation of all available EMB-01 nonclinical pharmacology and toxicology data, published clinical trial data on dual EGFR and cMET blockade, as well as, literature or public data on FDA-approved anti-EGFR therapies cetuximab and panitumumab. Such nonclinical data supported the proposed 1.67 mg/kg or a flat dose at 100mg/person starting dose of EMB-01 in human clinical study.

The primary endpoints for Phase I included assessment of safety profile comprising adverse events, changes in safety assessment parameters, tolerability through dose interruption and dose intensity, and determination of dose limiting toxicity. Secondary endpoints encompassed pharmacokinetic (“PK”) parameters including area under the concentration-time curve (“AUC”), maximum observed concentration (“C_{max}”), clearance, volume of distribution, and accumulation ratio. Additional secondary endpoints included evaluation of ADA incidence and preliminary antitumor activity metrics. The exploratory endpoint involved investigating the pharmacodynamic characteristics and immunogenicity of EMB-01.

In Phase II study, patients with advanced/metastatic EGFR mutant and/or cMET aberration NSCLC who progressed after standard treatment or patients who were intolerant to standard treatment were enrolled at the RP2D(s). The rationale for the Phase II study design is based on the clinical need to address acquired and primary resistance mechanisms in advanced or metastatic EGFR-mutant and/or cMET-altered NSCLC. While EGFR-targeted therapies, including first-, second-, and third-generation TKIs, have significantly changed advanced NSCLC, resistance inevitably develops — commonly through EGFR secondary mutations, MET amplification, or other molecular alterations. Additionally, complex disease such as cancer is a multifactorial condition, associated with a redundancy of disease-mediating receptors and ligands and crosstalk between the signaling pathways. Moreover, the concept of dual targeting of disease-modifying molecules may increase the antiproliferative effect and help to avoid the development of resistance. To address these gaps, the study enrolled patients with EGFR TKI failure or intolerance into five biomarker-defined cohorts to evaluate the therapeutic potential of dual targeting in molecularly stratified subgroups.

The Phase II portion aimed to evaluate the safety, tolerability and preliminary antitumor activity of EMB-01 at RP2D. In addition to its primary objectives, the study incorporated exploratory objectives to deepen understanding of EMB-01’s pharmacodynamic characteristics, such as soluble EGFR and cMET levels, as well as its exposure-response relationships. PK data, both intense and sparse, were pooled to assess population pharmacokinetics (“PK”) and interpatient variability, including the impact of factors like body weight, gender, and organ function. Primary endpoints focused on antitumor activity, safety, and tolerability, while secondary endpoints included progression-free survival (“PFS”), clinical benefit rate, and PK measures like AUC and C_{max}. For exploratory endpoints, pharmacodynamic markers were further investigated using modeling approaches to explore exposure-response relationships and variability.

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Demographic and baseline characteristics. A total of 115 patients diagnosed with advanced or metastatic solid tumors were enrolled, with the majority (103/115; 89.6%) having NSCLC. Specifically, NSCLC was diagnosed in 53 of 65 patients (81.5%) in the Phase I trial and all 50 patients (100%) in the Phase II trial. Across all 115 patients, the mean number of prior systemic anticancer therapy lines was 3.2 (standard deviation: 1.74), with a median of 3.0 (range: 0 to 11). As of July 25, 2023, the Phase I trial included 33 male patients (50.8%) and 32 female patients (49.2%), while the Phase II trial enrolled 18 male patients (36.0%) and 32 female patients (64.0%).

Eligible patients are required to be aged ≥ 18 years with measurable disease per RECIST v1.1. In Phase I, eligible patients had unselected (i.e. EGFR mutations or other gene aberrations unknown or unconfirmed) advanced/metastatic solid tumors including NSCLC refractory to standard therapy or no standard therapy is available or accessible, with an ECOG performance status of 0 or 1. In Phase II, eligible patients were those with advanced or metastatic NSCLC with EGFR and/or cMET aberrations confirmed and progressed on standard treatment or intolerant to standard treatment, with an ECOG performance status of 0 to 2.

Trial status. The trial was completed in July 2023 with a total of 115 patients enrolled. Phase I included 65 patients with advanced/metastatic solid tumors, while Phase II enrolled 50 NSCLC patients harboring an EGFR mutation and/or cMET aberration. Phase I of the study enrolled patients with histologically cytologically confirmed advanced solid tumors who were refractory to currently available therapies or have malignancies for which no effective treatment was available. In Phase II of the study, documented EGFR mutant and/or cMET aberrated NSCLC patients with disease progressed after the standard treatment were enrolled.

Safety results. EMB-01 was generally well-tolerated, with a manageable safety profile in heavily pre-treated patients with solid tumors at doses up to 1,600 mg once a week. The safety profile of EMB-01 was consistent with the known effects of EGFR and cMET inhibition. The RP2D was determined to be 1,600 mg once a week, based on safety data, PK, ADA assessments, PK/pharmacodynamic modeling, and preliminary efficacy results.

Efficacy results. EMB-01 demonstrated modest efficacy in heavily pretreated patients with advanced/metastatic solid tumors, including those with EGFR-mutant and/or cMET-aberrant NSCLC. In Phase I (65 patients), the confirmed best overall response included one partial response with a durable response of 76.1 weeks. In Phase II (50 patients), EMB-01 showed notable activity in Group 2 patients with EGFR C797S mutations, achieving a CBR of 30.8% and a median PFS of 15.4 weeks. Across both phases, the clinical benefit rate, defined as confirmed PR or stable disease ≥ 15 weeks) was 10.8% in Phase I and 20.0% in Phase II. These findings suggest that EMB-01 may provide clinical benefit, particularly to NSCLC patients with EGFR C797S mutations who have exhausted standard therapies.

Conclusion. EMB-01 has demonstrated an acceptable safety profile in patients with advanced solid tumors, and the preliminary efficacy signal results suggest its anti-tumor activities warrant further exploration in certain special types of advanced/metastatic solid tumors.

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Ongoing Phase Ib/II clinical trial of EMB-01 in patients with advanced/metastatic gastrointestinal cancers

We launched the Phase Ib/II study of EMB-01 in patients with advanced/metastatic gastrointestinal cancers in October and December 2021 in the United States and China, respectively. We completed the Phase Ib study in August 2023 and initiated the Phase II study in the same month. We were the sponsor of this clinical trial.

GI cancers, including mCRC, often overexpress EGFR and cMET. While anti-EGFR drugs such as cetuximab or panitumumab have been approved for the treatment of RAS/RAF wild-type mCRC in combination with chemotherapy in the first or second-line settings, most patients will eventually develop resistance due to crosstalk between EGFR and cMET pathways. Third-line treatment options, such as fruquintinib, regorafenib, or trifluridine/tipiracil (TAS-102) ± bevacizumab, provide limited efficacy.

EMB-01 has demonstrated its antitumor activity in preclinical and clinical studies with a RP2D of 1600 mg once weekly intravenously.

Trial design. A Phase Ib/II, multicenter, open-label study in China and the United States to evaluate the safety and efficacy of EMB-01 at the RP2D in patients with advanced gastrointestinal tumors, including gastric cancer, hepatocellular cancer, biliary tract cancer and CRC, who have failed standard therapies or no standard therapy available. Eligible patients were required to be ≥18 years old with previously heavily-treated mCRC, have an ECOG performance status of 0 or 1, and measurable disease per RECIST v1.1. Patients must not have had any gene alterations known to confer resistance to EGFR and/or cMET inhibitors. The Phase Ib portion of this trial is designed to evaluate the safety and tolerability of EMB-01 administered at the RP2D of 1,600 mg once weekly in patients with advanced gastrointestinal cancers who have failed standard therapies or for whom no standard therapy is available. The primary objective is to assess the safety and tolerability of EMB-01, as measured by adverse events, changes in safety, dose interruption, and dose intensity. A further primary objective is to characterize the PK profile and immunogenicity of EMB-01. The secondary objective is to evaluate the preliminary antitumor activity at the RP2D, with endpoints including best overall response, objective response rate, DOR, DCR, clinical benefit rate, and PFS. Exploratory objectives include investigating the pharmacodynamic characteristics of EMB-01, such as changes in levels of soluble EGFR and cMET following EMB-01 administration.

The Phase II portion of this trial aims to further estimate the preliminary antitumor activity of EMB-01 at the RP2D of 1,600 mg once weekly in the same patient population. The primary objective is to assess the antitumor efficacy of EMB-01, with the primary endpoint being the evaluation of anti-tumor activity through best overall response, objective response rate, DOR, DCR, clinical benefit rate, and PFS. Secondary objectives focus on additional characterization of PK parameters and immunogenicity using sparse PK blood samples, as well as further evaluation of safety and tolerability, including adverse events and changes in safety assessment parameters. Exploratory objectives in Phase II continue to investigate pharmacodynamic characteristics, such as changes in soluble EGFR and cMET levels after EMB-01 treatment. These comprehensive objectives and endpoints are designed to inform the efficacy, safety, PK, and pharmacodynamic profile of EMB-01 in advanced gastrointestinal cancers.

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Phase Ib enrolled patients with EGFR and/or cMET overexpression or gene alterations, while Phase II included patients regardless of EGFR/cMET expression or gene alteration status. Key eligibility criteria included age ≥ 18 , ECOG performance status of 0 or 1, measurable disease per RECIST v1.1, and absence of known resistance-conferring gene alterations to EGFR or cMET inhibitors.

Trial status. As of March 6, 2025, 52 patients with gastrointestinal cancers, including 48 with mCRC, were enrolled in this Phase Ib/II study and enrollment has been concluded. In Phase Ib, 27 patients were enrolled, including 1 gastric cancer, 1 hepatocellular cancer, 2 biliary tract cancers and 23 CRC. In Phase II, 25 patients were enrolled, all of whom were CRC. We expect to complete the Phase Ib/II trial in the fourth quarter of 2025.

Safety results. As of March 6, 2025, treatment-related adverse events were reported in 98% of patients, with 67% experiencing Grade ≥ 3 treatment-related adverse events. The most common treatment-related adverse events (“TRAES”) ($\geq 30\%$ incidence) by preferred term included rash (any grade: 60%; Grade ≥ 3 : 25%), myalgia (any grade: 52%; Grade ≥ 3 : 2%), paronychia (any grade: 40%; Grade ≥ 3 : 8%), and hypoalbuminemia (any grade: 35%; Grade ≥ 3 : 2%). Grade 1/2 infusion-related reactions were observed in two patients (4%). Skin toxicities such as rash observed with EMB-01 are commonly reported with other agents in this class. Overall, these findings indicate that EMB-01 has a safety profile comparable to other EGFR targeted antibodies and is generally well-tolerated, with manageable adverse events.

The following table sets forth the incidence of TRAES in 48 mCRC patients in this trial:

TRAES ($\geq 15\%$) by Preferred Term, n (%)	All Grades	Grade ≥ 3
Rash	29 (60)	12 (25)
Myalgia	25 (52)	1 (2)
Paronychia	19 (40)	4 (8)
Hypoalbuminemia	17 (35)	1 (2)
Alanine aminotransferase increased	14 (29)	1 (2)
Dermatitis acneiform	12 (25)	9 (19)
Aspartate aminotransferase increased	9 (19)	0
Blood bilirubin increased	9 (19)	1 (2)
Hypokalemia	8 (17)	0
Hypomagnesaemia	8 (17)	1 (2)
Pruritus	8 (17)	0
Pyrexia	8 (17)	0

Abbreviations: TRAE, treatment-related adverse event.

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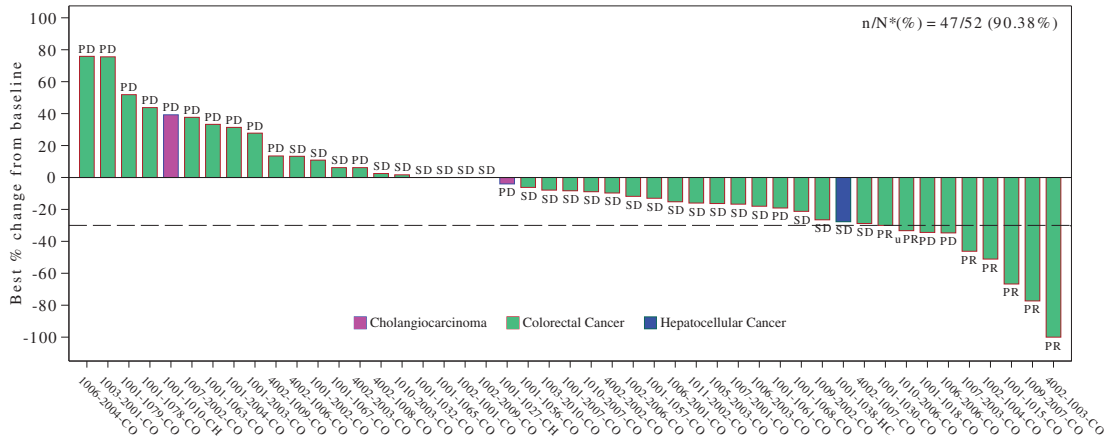
Efficacy results. Efficacy data from 44 evaluable mCRC patients were analyzed. In the overall population, seven cases of partial response and 24 cases of stable disease were observed, leading to an ORR of 16% (7/44, 95% CI: 6.6-30.1), DCR of 71% (31/44, 95% CI: 54.8-83.2) and mDOR of 32 weeks (95% CI: 16.0-NE) as of March 6, 2025. The DCR and ORR of EMB-01 reported in this trial indicated its preliminary efficacy for the treatment of mCRC, compared with the DCR and ORR of other SoC treatments such as regorafenib, TAS-102, and fruquintinib reported in their published clinical data. Among 29 patients with left-sided, RAS/RAF wild-type mCRC, who had a median of three prior lines of therapy (range: 1-7) and no prior exposure to fruquintinib, regorafenib, or TAS-102, seven patients achieved partial response, with six confirmed partial responses, and 17 achieved stable disease (including 11 tumor-shrinking stable disease). The ORR was 24% (95% CI: 10.3-43.5), the DCR was 83% (95% CI: 64.2-94.2), and the clinical benefit rate was 55.2% (95% CI: 35.7-73.6). For the six confirmed responders, the median duration of response (mDOR) was 32 weeks, with two patients still on treatment as of March 6, 2025, and an estimated 24-week DOR rate of 80% (95% CI: 20.4-96.9). The longest treatment duration observed was 47 weeks.

Subgroup analyses revealed differences based on prior anti-EGFR therapy and liver metastases. Among 18 patients who had progressed on prior anti-EGFR therapy, the ORR was 22%, and the DCR was 78%. In anti-EGFR treatment-naïve patients (n=11), the ORR was 27%, and the DCR increased to 91%. For patients with liver metastases (n=17), the ORR was 24%, and the DCR was 76%, whereas patients without liver metastases (n=12) had an ORR of 25% and a higher DCR of 92%.

In 15 mCRC patients who were classified into an unfavorable subgroup due to right-sided, RAS/RAF-mutant or heavy pretreatment, including prior exposure to fruquintinib, regorafenib, or TAS-102, EMB-01 showed limited efficacy. In this cohort, no partial responses were observed, and the DCR was 47%.

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The following chart illustrates the best percentage change in tumor size from baseline for 52 efficacy evaluable patients across three cancer types: cholangiocarcinoma, mCRC, and hepatocellular carcinoma, as of March 6, 2025. Among 44 evaluable mCRC patients, seven had partial response, and 24 achieved stable disease (including 11 tumor-shrinking stable disease), leading to an ORR of 15.9% (7/44) and a DCR of 70.5% (31/44).



- Best Overall Response is annotated: CR=Complete Response, PR=Partial Response, PD=Progressive Disease, SD=Stable Disease, uPR=Unconfirmed PR (not confirmed by a subsequent PR at least 4 weeks apart before progression).
 - Acronym after subject: CH=Cholangiocarcinoma, GC=Gastric Cancer, CO=Colorectal Cancer, HC=Hepatocellular Cancer.

Source: Company data

Conclusion. EMB-01 monotherapy demonstrated efficacy signals in heavily pretreated mCRC patients with left-sided, RAS/RAF wild-type tumors who had no prior exposure to fruquintinib, regorafenib, or TAS-102. Moreover, EMB-01 showed notable activity in mCRC patients refractory to prior anti-EGFR therapy, as well as in those with active liver metastases, indicating its potential benefit in these challenging subgroups.

At a dose of 1,600 mg administered intravenously on a weekly schedule, EMB-01 exhibited an acceptable safety profile, with manageable treatment-related adverse events. These results support the need for further investigation of EMB-01 in larger, well-defined patient cohorts to confirm its efficacy and safety in the treatment of mCRC.

Phase Ib clinical trial of EMB-01 in combination with chemotherapy for the treatment of unresectable/metastatic CRC

We submitted the IND application for the Phase Ib trial of EMB-01 for the treatment of unresectable/metastatic CRC with the NMPA in November 2023 and received approval from the NMPA in January 2024.

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Trial design. This is a Phase Ib, open-label study is planned to evaluate EMB-01 in combination with various chemotherapies in mCRC patients across different lines of prior treatment. The trial aims to assess the safety and tolerability of EMB-01 in combination with irinotecan, TAS-102, mFOLFOX6, or FOLFIRI, and to determine the MTD and/or recommended Phase 2 combination dose. Secondary objectives include PK characterization of EMB-01, preliminary antitumor activity, and immunogenicity when combined with different chemotherapy regimens. Exploratory objectives are to investigate relationships between PK, pharmacodynamic biomarkers (soluble EGFR and cMET), efficacy, and safety endpoints, as well as correlations between biomarkers and clinical outcomes. Primary, secondary, and exploratory endpoints are defined accordingly.

Trial status. We expect to initiate this trial after obtaining preliminary readouts from the planned Phase II EMB-01 monotherapy study in mCRC. See “— Clinical Development Plan” for details.

License, Rights and Obligations

We are developing EMB-01 in-house and own the global rights to develop and commercialize EMB-01.

Clinical Development Plan and Regulatory Communications

Clinical development strategy

Our clinical trial plan for EMB-01 reflects a deliberate evolution from broad exploratory investigation to indication-specific development, guided by emerging clinical signals and mechanistic rationale. Beginning with a first-in-human clinical trial on EMB-01 monotherapy for the treatment of advanced/metastatic solid tumors in U.S. and in China (the “**Phase I/II Clinical Trial for Tumor Mono**”), our plan progressively refined the focus toward gastrointestinal cancers based on EGFR-driven biology with a Phase Ib/II clinical trial on EMB-01 monotherapy for the treatment of a basket of advanced/metastatic gastrointestinal cancers including gastric cancer, hepatocellular cancer, biliary tract cancer and CRC (collectively, the indications as the “**GI Cancers**”, the clinical trial as the “**Phase Ib/II Clinical Trial for GI Mono**”), culminating in a dedicated Phase II clinical trial on EMB-01 monotherapy for the treatment of mCRC in 3L setting (the “**Phase II Clinical Trial for mCRC Mono**”).

- Phase I/II Clinical Trial for Tumor Mono (Phase I Completed: December 2018 — September 2021; Phase II Completed: September 2021 — July 2023): Initially, we conducted a first-in-human Phase I/II clinical trial for solid tumor monotherapy. This trial was designed to evaluate EMB-01’s safety and tolerability in patients with advanced/metastatic solid tumors, with the goal of determining the MTD and/or RP2D and to assess general safety, tolerability, and preliminary efficacy across various cancer types. While this trial provided broad initial insights, our strategic focus quickly narrowed.

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- Phase Ib/II Clinical Trial for GI Mono (Phase Ib Completed: October 2021 — August 2023; Phase II ongoing): In light of the compelling preclinical data demonstrating robust potency of EMB-01 in GI tumor models and the known therapeutic benefit of EGFR antibodies such as cetuximab in CRC, we decided to prioritize GI cancers for further clinical investigation. Following the determination of RP2D in the Phase I portion of the Phase I/II Clinical Trial for Tumor Mono, we initiated a Phase Ib/II trial in October 2021 in the United States and in December 2021 in China and to specifically evaluate EMB-01 monotherapy in a range of gastrointestinal cancers, including gastric, hepatocellular, biliary tract and colorectal cancer.
- Phase II Clinical Trial for mCRC Mono (expected trial initiation around year end of 2025): Our decision to initiate a separate Phase II trial for EMB-01 in third-line mCRC, despite its inclusion in the ongoing Phase Ib/II Clinical Trial for GI Mono, is a strategic move driven by the encouraging efficacy signals and manageable safety observed specifically in mCRC patients during the Phase Ib/II Clinical Trial for GI Mono. As of March 6, 2025, among 29 patients with left-sided, RAS/RAF wild-type mCRC in this trial, seven achieved partial response (24.1% ORR) and 17 achieved stable disease (including 11 tumor-shrinking stable disease), resulting in a DCR of 82.8%. The median DOR for six confirmed responders was 32 weeks, with two partial responses still on treatment at data cutoff. See “— Summary of Clinical Trial Results — Ongoing Phase Ib/II Clinical Trial of EMB-01 in Patients with Advanced/Metastatic Gastrointestinal Cancers” in this section for more details. The Phase II Clinical Trial for mCRC Mono is an independent study and not part of the Phase Ib/II Clinical Trial for GI Mono. This dedicated Phase II trial allows for a more focused and robust assessment of EMB-01’s effectiveness and safety within a homogeneous patient population, enabling a trial design with fine-tuning dosing regimens specifically optimized for this particular indication. Such a focused approach is crucial for generating the robust data needed for BLA-enabling Phase III trial and accelerates the development pathway towards addressing the medical needs in late-stage mCRC management, where current treatment options offer limited survival benefits.

The strategic evolution from advanced/metastatic solid tumors to GI Cancers, and ultimately to mCRC, was a deliberate decision driven by emerging clinical and mechanistic insights. This progression was not mandated by, nor undertaken in response to, any requirements or conditions imposed by the NMPA or FDA. The relevant regulatory authorities have not raised any objections to the aforementioned clinical plans or to our initiation of the next phase of the clinical trial. For details of the material communications and/or regulatory assurance obtained from the NMPA and/or FDA, see “— Material Communications with Competent Authorities.” We believe this deliberate evolution in trial strategy has not resulted in any material adverse impact on the design, assessment framework, cost structure, timeline, or resource allocation for the clinical development of EMB-01. The progression has enhanced trial design by narrowing patient populations for precision and potentially defined indication and has streamlined costs through more efficient resource consolidation.

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We currently do not plan to pursue Phase III clinical trials for EMB-01 in advanced/metastatic solid tumors or gastrointestinal cancers other than mCRC. These earlier-stage trials provided valuable safety and mechanistic insights; however, based on emerging clinical data, biological rationale, and medical need, we have strategically prioritized mCRC as the lead indication for EMB-01. Going forward, EMB-01’s development will focus on third-line monotherapy and combination therapy in second-line and third-line mCRC settings. Meanwhile, in line with our corporate strategy to optimize resource allocation and enhance cost-effectiveness across our clinical development portfolio, we plan to prioritize the advancement of our ongoing clinical programs for EMB-01 in China and therefore do not intend to submit, in the near term, IND applications for its Phase II trial for mCRC monotherapy or Phase Ib trial for mCRC combination therapy to the FDA. We believe this focus will help consolidate our efforts, maintain operational efficiency and streamline regulatory pathways of EMB-01 in China by avoiding parallel late-stage regulatory submissions in multiple jurisdictions. By prioritizing China as the lead development jurisdiction, we are able to focus regulatory interactions and clinical execution under the NMPA framework, thereby reducing regulatory complexity and expediting China-centric development. We expect to be the marketing authorization holder (“MAH”) of EMB-01 in all jurisdictions following its commercialization.

- EMB-01 monotherapy in the third-line mCRC: We have submitted an IND application for the Phase II Clinical Trial for mCRC Mono with the NMPA in March 2025 and received the IND approval in May 2025. We expect to initiate this trial around year end of 2025.
- EMB-01 in combination with chemotherapy: As a combination strategy, we are also planning a Phase Ib study of EMB-01 in combination with chemotherapies in second-line and third-line settings (the “**Phase Ib Clinical Trial for mCRC Combo**”). We have obtained IND approval for the Phase Ib Clinical Trial for mCRC Combo from the NMPA in January 2024. We expect to initiate this trial following the interim data readout from the planned Phase II Clinical Trial for mCRC Mono in China.

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Material communications with competent authorities

The following table sets forth a summary of material communications with regulatory authorities regarding EMB-01:

Regulatory Communication	IND/Amendment Scope	Corresponding Clinical Trial	Trial Inter-relationship
Submission of IND application to the NMPA in September 2018	Umbrella approval** for Phase I/II clinical trial for the treatment of advanced/metastatic solid tumors	Following the IND approvals, we initiated the Phase I/II Clinical Trial for Tumor Mono in China and the United States	N/A
IND approval from the NMPA in November 2018	Phase I portion: <ul style="list-style-type: none"> Primary objectives: to evaluate the safety and tolerability of EMB-01 when administered intravenously and to determine MTD and/or the RP2D(s). Secondary objectives: to characterize PK, estimate preliminary antitumor activity and evaluate the incidence of immunogenicity 	<ul style="list-style-type: none"> Phase I Completed: December 2018 – September 2021 Phase II Completed: September 2021 – July 2023 	
Submission of IND application to the FDA in August 2018	Phase II portion: <ul style="list-style-type: none"> Primary objectives: to estimate preliminary antitumor activity at RP2D(s), and continue to evaluate the safety and tolerability of EMB-01 Secondary objective: to continue to characterize PK and immunogenicity of EMB-01 		
IND approval from the FDA in September 2018	Umbrella approval** for Phase I/II clinical trial of EMB-01 for the treatment of advanced/metastatic gastrointestinal cancers	Phase I/II Clinical Trial for GI Mono in China and the United States	The Phase I/II Clinical Trial for GI Mono is based on the RP2D obtained from the Phase I/II Clinical Trial for Tumor Mono
Communication with the NMPA in September 2021 on the proposed trial initiation*	Phase I portion: <ul style="list-style-type: none"> Primary objectives: to assess the safety and tolerability of EMB-01 at RP2D, and characterize PK and immunogenicity of EMB-01 in patients with GI cancers Secondary objective: to evaluate the antitumor activity of EMB-01 at RP2D in patients with GI cancers 	<ul style="list-style-type: none"> Phase I Completed: October 2021 – August 2023 Phase II ongoing 	
Obtaining approval to proceed with the trial from the NMPA in December 2021*	Phase II portion: <ul style="list-style-type: none"> Primary objective: to evaluate the antitumor activity of EMB-01 at RP2D in GI patients Secondary objectives: to further characterize the PK and immunogenicity and evaluate the safety and tolerability of EMB-01 at RP2D in patients with GI cancers 		
Submission of an IND amendment to the FDA to provide a new protocol in September 2021 *			
Completing IND amendment under FDA to proceed with the trial from the FDA in October 2021 *			
Submission of IND application to the NMPA in November 2023	Phase I/II clinical trial in combination with chemotherapy for the treatment of mCRC	The Phase I/II Clinical Trial for mCRC Combo in China	The decision to submit IND application of the Phase I/II Clinical Trial for mCRC Combo is based on the results observed in mCRC patients during the Phase I/II Clinical Trial for GI Mono, together with robust preclinical data from animal model studies and literature evidence
IND approval from the NMPA in January 2024	Phase I portion: <ul style="list-style-type: none"> Primary objectives: to assess the safety and tolerability of EMB-01 in combination with irinotecan, TAS-102, mFOLFOX6, or FOLFIRI, and determine the MTD and/or recommended Phase II combination dose (RP2CD) Secondary objectives: to characterize PK, estimate preliminary antitumor activity and immunogenicity of EMB-01 when combined with different chemotherapy regimens 	<ul style="list-style-type: none"> Expected trial initiation pending interim data readout of Phase II Clinical Trial for mCRC Mono 	
Submission of the IND application to the NMPA in March 2025	Phase II clinical trial for the treatment of mCRC	Phase II Clinical Trial for mCRC Mono in China	The decision to submit IND application of the Phase II Clinical Trial for mCRC Mono is based on the results observed in mCRC patients during the Phase I/II Clinical Trial for GI Mono
IND approval from the NMPA in May 2025	<ul style="list-style-type: none"> Primary objectives: to evaluate the efficacy, safety and tolerability of EMB-01 at different dose levels Secondary objectives: to evaluate additional efficacy endpoints, characterize PK and evaluate the immunogenicity of EMB-01 at different dose levels 	<ul style="list-style-type: none"> Expected trial initiation around the end of 2025 	

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Notes:

- * Up to the Latest Practicable Date, the only amendment to the existing IND approval of EMB-01 that required approval from the competent regulatory authorities was the amendment supplementing the clinical protocol for the Phase Ib/II Clinical Trial for GI Mono under the existing IND for the Phase I/II Clinical Trial for Tumor Mono. In China, this amendment was approved by the NMPA following regulatory consultation, and in the United States, the amendment became effective through the FDA's implied approval process. Other than the above, during the Track Record Period and up to the Latest Practicable Date, we implemented changes of clinical trial protocols of EMB-01 in consultation with investigators and with the approval of the relevant ethics committees of the study institutions. These protocol refinements primarily involved updates to improve operational consistency and study conduct, and did not affect the safety or rights of trial subjects, nor did they compromise the reliability or robustness of the clinical data generated. Accordingly, such refinements did not require approval from the competent regulatory authorities.
- ** Each phase of a combined clinical trial of EMB-01 is equivalent to meeting the objectives and endpoints typically associated with conventional Phase I and/or Phase II clinical trials and therefore is standalone. The IND approval or regulatory clearance serves as an umbrella approval for these combined clinical trials of EMB-01. No further approval from the NMPA or FDA is required before proceeding to the next phase of each combined clinical trial of EMB-01.

As of the Latest Practicable Date, we have not received any regulatory agency's concerns or objections to our clinical development plans.

EMB-01, whose chemical name is bafisontamab, is classified as a Class 1 innovative biological products in all indications in China, and as advised by Frost & Sullivan, EMB-01 is classified as an investigational new drug under the U.S. FDA regulatory framework. For each indication under clinical development, EMB-01 follows the standard regulatory pathway for novel biologics.

Looking ahead, we expect that all the indications of EMB-01 currently under development will be regulated as one single product under the same drug certificate. Under the NMPA regulatory regime, upon the first approval of new drug application of EMB-01 for an indication such as mCRC (whether as monotherapy or combination therapy), the product will be registered under a drug registration certificate with a specific drug approval number, authorizing its use in treating that target indication. According to Frost & Sullivan, as the common practice, unless dosage forms, strengths and route of administration are changed, the registration of newly approved use of a cancer drug such as EMB-01 in other indications will remain registered with the NMPA under the same drug approval number after the first marketing approval. As evidenced by numerous precedent cases in oncology drug development, this regulatory pathway of registering multiple indications of one drug product as one single product under the same drug approval number is well established.

Until now, the dosage form, strength and route of administration of EMB-01 are the same in each indication. Therefore, under the NMPA regulatory framework, once EMB-01 receives its initial approval for a specific indication, it will be registered under one drug registration certificate with a designated drug approval number. If there are no changes in dosage forms, strengths and route of administration, any subsequent approvals for EMB-01 in other indications will be registered and regulated as different uses of a single product under the same drug approval number.

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R&D Expenses for Core Product

In 2023, 2024 and the nine months ended September 30, 2024 and 2025, expenses in relation to R&D activities incurred for our Core Product EMB-01 were RMB63.3 million, RMB24.8 million, RMB22.1 million and RMB15.5 million, respectively, accounting for 34.3%, 20.2 %, 23.8% and 16.0% of our total R&D expenses for the corresponding periods. During the Track Record Period, we have been primarily engaged in the research and development of EMB-01 since the initiation of its first-in-human clinical trial in 2018. The decline in EMB-01-related R&D expenses during this period reflects the natural progression and cyclical nature of clinical trial activities. In 2023, two major trials were concurrently active — the Phase II portion of the Phase I/II clinical trial for advanced/metastatic solid tumors and the Phase Ib/II clinical trial for advanced/metastatic gastrointestinal cancers — driving EMB-01-related expenses to RMB63.3 million, or 34.3% of our total R&D expenses for the year. In 2024, as only the Phase II portion of the GI monotherapy trial remained active and patient enrollment was nearing completion, EMB-01-related expenses decreased to RMB24.8 million, or 20.2% of total R&D expenses. The difference in patient enrollment scale — 115 patients in the Phase I/II tumor monotherapy trial versus 52 patients in the Phase Ib/II GI monotherapy trial as of March 2025 — also contributed to the temporary decline. For the nine months ended September 30, 2025, EMB-01-related expenses further decreased to RMB15.5 million, or 16.0% of total R&D expenses, as we were completing the Phase II portion of the GI monotherapy trial following patient enrollment completion in March 2025. During this period, our primary activities shifted to IND preparation for the planned Phase II trial of EMB-01 monotherapy in third-line mCRC, which is inherently less resource-intensive and therefore resulted in lower R&D spending at this stage.

Looking ahead, we are preparing to initiate two new clinical trials for EMB-01 around the end of 2025 and beyond: (i) a dedicated Phase II trial for monotherapy in third-line mCRC, and (ii) a Phase Ib trial in combination with chemotherapy in multiple lines of treatment, following the interim data readout from the planned Phase II monotherapy trial. In addition, we expect to commence a Phase III clinical trial of EMB-01 in mCRC patients in China in 2027. R&D expenses for these planned trials will primarily include CRO and site management costs, CMC expenses, and labor costs associated with our clinical development team. These activities are expected to significantly increase our R&D investment beginning in 2026. Accordingly, our proposed [REDACTED] is strategically intended to raise the necessary funds to support these upcoming trials and to accelerate the development and commercialization of EMB-01, reaffirming our commitment to advancing our Core Product.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EMB-01 SUCCESSFULLY.

EMB-06 (BCMA/CD3), Our Key Product

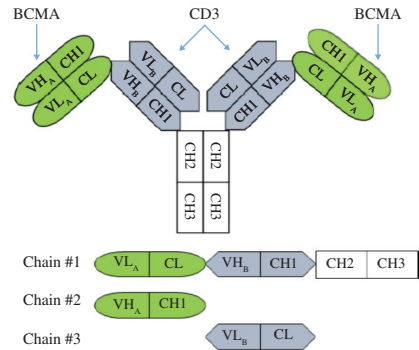
EMB-06 is a recombinant humanized bispecific antibody against BCMA and CD3. It is being developed for the treatment of multiple myeloma (MM) and autoimmune diseases. Bispecific T-cell engagers (TCEs) have emerged as transformative therapeutics in oncology, and more recently, in autoimmune diseases. Leveraging their ability to simultaneously engage tumor-associated antigens and CD3, TCEs can promote T cell-mediated antitumor activity. However, the development of conventional TCEs faces several challenges, including cytokine release syndrome, on-target/off-tumor toxicity, and limited efficacy against complex resistance mechanisms. By integrating FIT-Ig and MAT-Fab bispecific platforms with our proprietary CD3 binder panel, we can design TCEs that enable optimal proximal epitope positioning between the tumor-associated antigens and CD3, thereby facilitating robust T-cell activation while maintaining reduced CD3 binding affinity. This spatial configuration, in combination with our CD3 binder panel encompassing a range of binding affinities, enables us to develop more optimized TCEs with an appropriately tuned CD3 binding affinity. This ensures potent target cell killing while simultaneously minimizing the risk of cytokine release syndrome.

The structure of EMB-06 is based on our FIT-Ig platform, so the binding domains are connected in a crisscross orientation without peptide linkers or artificial mutations. The two Fab fragments of the anti-BCMA antibody, positioned on the “outside” regions of the molecular structure, specifically bind to BCMA expressed on the surface of tumor cells. Simultaneously, the anti-CD3 antibody, located in the “inside” region, binds to CD3 expressed on the surface of T cells. Upon binding to BCMA on tumor cell surface, EMB-06 recruits and activates CD3 expressing T lymphocytes, thereby mediating the cytotoxic effect of T lymphocytes against tumor cells. Our experiments demonstrate that BCMA and CD3 are predominantly bound on the same side, either left or right, in a so-called cis-orientation. This orientation brings the T cell and the B cell into closer proximity, thereby enhancing T cell-mediated cytotoxicity. Additionally, this configuration allows for reduced CD3 binding affinity, which mitigates potential adverse effects such as cytokine release syndrome. Two mutations, Leu234Ala and Leu235Ala, are introduced into the Fc fragment of EMB-06 to abolish antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity activity.

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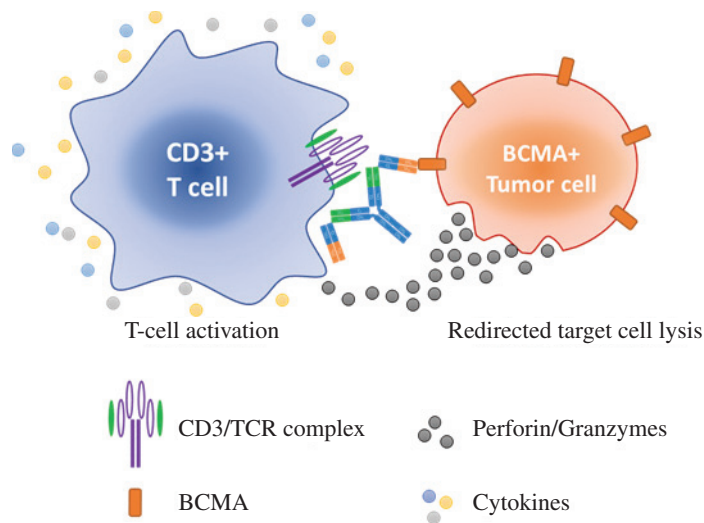
Drug Design and Mechanism of Action

The molecular structure of EMB-06 is illustrated below:



Preclinical and clinical evaluations have validated EMB-06's favorable safety profile, characterized by high efficacy with low cytokine release syndrome and neurotoxicities incidence. These favorable safety results are attributable to EMB-06's optimized format and binding affinities, as well as use of our proprietary CD3 binder. Furthermore, EMB-06 serves as a proof-of-concept, illustrating the capability of our platform to efficiently design optimized TCE candidates, supply initial *in vitro* and *in vivo* validation data, and subsequently translate this preclinical evidence into clinical outcomes. We consider this approach to be essential for advancing future TCE candidates in the fields of oncology and autoimmune diseases.

The following diagram illustrates the mechanism of action of EMB-06:



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Market Opportunities and Competition

Multiple Myeloma (MM)

MM is a cancer of the plasma cells in the bone marrow, and it is characterized by the uncontrolled growth of antibody-producing white blood cells. MM leads to extensive skeletal destruction, including osteolytic lesions, osteopenia, and pathologic fractures. Globally, the incidence of MM is rising, driven by factors such as aging populations and advancements in diagnostic methods. In China, the number of new MM cases reached 31.8 thousand in 2024 with a CAGR of 2.6% from 28.8 thousand in 2020. The incidence is projected to rise to 36.4 thousand by 2030 at a CAGR of 2.2% from 2024 to 2030, and further to 39.4 thousand by 2034 at a CAGR of 2.0% from 2030 to 2034. The MM drug market size in China reached US\$1.0 billion in 2024, growing at a CAGR of 7.7% from 2020 to 2024 and is expected to expand to US\$4.0 billion by 2030 at a CAGR of 24.9% from 2024 to 2030, and further to US\$6.0 billion by 2034 at a CAGR of 10.7% from 2030 to 2034.

Current treatment approaches for MM include induction therapy, maintenance therapy, and hematopoietic stem cell transplantation. Induction regimens often consist of combinations such as bortezomib, lenalidomide, and dexamethasone, among others. Maintenance therapy typically involves agents like lenalidomide, bortezomib, and proteasome inhibitors for high-risk patients. Autologous hematopoietic stem cell transplantation remains a cornerstone for eligible patients, while clinical trials exploring CAR-T therapy and novel agents are ongoing. Despite advancements, significant limitations persist, such as drug resistance, high relapse rates, and treatment-related toxicities pose challenges to long-term disease control. While therapies like proteasome inhibitors and immunomodulatory drugs have improved outcomes, patients with aggressive subtypes such as non-hyperdiploid-MM or those unable to tolerate intensive treatment often experience poorer prognoses. Moreover, access to advanced therapies, such as CAR-T, remains limited due to high manufacturing costs and infrastructure constraints driven by the complexity of personalized cell engineering, stringent quality control requirements, and the need for specialized biomanufacturing facilities, underscoring the need for more affordable and broadly accessible treatment options.

BCMA and CD3 are critical targets in the treatment of MM due to their pivotal roles in disease biology and immune modulation. BCMA, a member of the tumor necrosis factor receptor superfamily, is highly expressed on malignant plasma cells but has limited expression on normal tissues, making it an ideal target for therapies with minimal off-target effects. It plays a key role in promoting plasma cell survival and proliferation through activation of pathways like NF- κ B and PI3K/AKT, which are often dysregulated in MM. Targeting BCMA disrupts these survival signals, leading to apoptosis of myeloma cells. CD3, on the other hand, is a critical component of the T-cell receptor complex and plays an essential role in T-cell activation. By engaging CD3, immune-based therapies, such as TCEs, recruit and activate cytotoxic T cells to specifically attack myeloma cells expressing BCMA. This dual-targeting mechanism leverages the immune system to overcome the immune evasion strategies employed by MM.

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As of the Latest Practicable Date, there are two marketed BCMA/CD3 bispecific antibodies for the treatment of MM available in China. The following table summarized selected information:

China Marketed Products								
Product	Company	Target	Drug Type	Indication	Mono/Combo	LOT	First Posted Date	Country
ELREXFIO	Pfizer	BCMA/CD3	Bispecific Antibodies	Multiple Myeloma	Mono	Last line	2025/3/4	China
TECVAYLI	Johnson & Johnson	BCMA/CD3	Bispecific Antibodies	Multiple Myeloma	Mono	Last line	2024/6/18	China

Source: FDA, EMA, PMDA, NMPA, Frost & Sullivan

The following table summarizes the information of clinical-stage BCMA/CD3 bispecific antibodies for the treatment of MM in China as of the Latest Practicable Date:

China Pipelines							
Product	Company	Target	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date
EMB-06	Our company	BCMA/CD3	Multiple Myeloma	II	Mono	Third Line/ Last-Line	2021/02/03
Etentamig	AbbVie	BCMA/CD3	Multiple Myeloma	III	Mono	Third Line/ Last Line	2023/12/06
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Multiple Myeloma	II	Mono	Second Line/ Third Line/ Last Line	2025/03/12
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Multiple Myeloma	II	Combo	Second Line/ Third Line/ Last Line	2025/03/11
CM336	Keymed Biosciences	BCMA/CD3	Multiple Myeloma	III	Mono	Third Line/ Last Line	2025/9/18
YKST02	Excyte Biopharma Ltd	BCMA/CD3	Multiple Myeloma	I	Mono	Third Line/ Last Line	2024/05/08
TQB2934	Chiatai Tianqing	BCMA/CD3	Multiple Myeloma	I	Mono	Second Line/ Third Line/ Last Line	2022/12/12

Source: NMPA, CDE, Frost & Sullivan

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Autoimmune diseases

Autoimmune diseases encompass over 100 different types of disorders, in which the body’s immune system mistakenly attacks its own tissues and organs. These diseases can affect almost any part of the body, including the heart, brain, nerves, muscles, skin, eyes, joints, lungs, kidneys, glands, digestive tract, and blood vessels. Rheumatoid arthritis, systemic lupus erythematosus, and inflammatory bowel disease are among the most prevalent autoimmune conditions globally. In 2024, the autoimmune disease drug market size in China reached US\$4.6 billion as compared to US\$2.5 billion in 2020, growing at a CAGR of 15.9% from 2020 to 2024 and is projected to reach US\$18.4 billion by 2030, representing a CAGR of 26.2% from 2024 to 2030 and further reach US\$35.2 billion by 2034, with a CAGR of 22.7% from 2030 to 2034. Globally, the autoimmune disease drug market is driven by unmet medical needs, with over 300 medicines and vaccines currently in clinical development, targeting conditions like autoimmune arthritis, lupus, psoriasis, inflammatory bowel disease, and type 1 diabetes.

Current treatments for autoimmune diseases primarily rely on systemic steroids, non-steroidal anti-inflammatory drugs, glucocorticoids, and disease-modifying anti-rheumatic drugs. While effective in alleviating inflammation, pain, and other symptoms, these therapies are limited to symptomatic relief and do not address the underlying causes of the diseases. Moreover, long-term use often leads to significant side effects, such as infections, organ damage, and treatment resistance. Targeted biologics, such as anti-TNF antibodies and interleukin inhibitors, including IL-6 and IL-17, represent a significant advancement in therapy by addressing specific pathways involved in autoimmune responses. However, despite their efficacy, nearly 47% of rheumatoid arthritis patients treated with TNF- α inhibitors and 42% of systemic lupus erythematosus patients treated with BlyS inhibitors fail to achieve sustained therapeutic responses. This underscores the urgent need for novel therapies with improved mechanisms to achieve disease remission and prevent irreversible damage. BCMA-targeted TCEs represent a transformative approach in autoimmune disease treatment. BCMA is commonly found on plasma cells and can also be found on B cells. B cells and plasma cells play a central role in autoimmune disease pathogenesis by contributing to the generation of pathogenic autoantibodies and immune dysregulation. Targeting BCMA can be an effective approach for depleting pathogenic plasma cells, offering therapeutic potential for diseases like systemic sclerosis, Sjogren’s syndrome, idiopathic inflammatory myositis and rheumatoid arthritis.

Recent clinical data highlight the broad immunological impact and commercial potential of BCMA-targeted TCEs. In patients with systemic sclerosis, Sjogren’s syndrome, and inflammatory myositis, teclistamab (BCMA/CD3 TCE) has demonstrated significant disease score improvements. The therapy also exhibited a manageable safety profile, with only mild cytokine release syndrome and transient infections. This potential to reset the immune environment rather than merely suppress symptoms positions BCMA-targeted TCEs as a next-generation therapeutic strategy for autoimmune diseases and paves the way for long-term disease control.

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The following table summarizes the information of clinical-stage BCMA/CD3 bispecific antibodies for the treatment of autoimmune diseases globally and in China:

Global Pipelines								
Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/Combo	First Posted Date	Country
EMB-06	Our Company	BCMA/CD3	Bispecific Antibody	Autoimmune Diseases	I	Mono	2024/04/25	China
REGN5459	Regeneron	BCMA/CD3	Bispecific Antibody	Lupus Nephritis	I	Mono	2025/05/16	France
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I	Mono	2025/08/26	China
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I/II	Mono	2025/11/14	China
CM336/ OM336	Keymed Biosciences, Ouro Medicines	BCMA/CD3	Bispecific Antibody	Immune Thrombocytopenia	I/II	Mono	2025/9/01	China
				Autoimmune Cytopenias	I	Mono	2025/7/24	Australia
				Active Sjogren's Disease, Idiopathic Inflammatory Myopathy	I	Mono	2025/10/22	Australia, New Zealand

China Pipelines								
Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/Combo	First Posted Date	Country
EMB-06	Our Company	BCMA/CD3	Bispecific Antibody	Autoimmune Diseases	I	Mono	2025/7/29	China
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I	Mono	2025/08/26	China
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I/II	Mono	2025/11/14	China
CM336	Keymed Biosciences	BCMA/CD3	Bispecific Antibody	Immune Thrombocytopenia	I/II	Mono	2025/9/18	China

Source: Clinical trials, Frost & Sullivan

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Competitive Advantages

EMB-06 exhibits distinct competitive advantages in both therapeutic efficacy and industrial scalability.

- Therapeutic safety and efficacy. EMB-06 demonstrates an optimized safety and tolerability profile, featuring reduced toxicity, minimal risk of cytokine release syndrome, and excellent overall tolerability. EMB-06 was rationally engineered with reduced CD3 binding affinity to minimize excessive T-cell activation, combined with a 2+2 Fabs-in-tandem format that enhances tumor-targeting specificity by dual epitope engagement. This design balances potent antitumor activity with controlled cytokine release. These attributes position EMB-06 as an attractive candidate for autoimmune indications where long-term safety is paramount. Clinical results from the Phase I/II trial in patients with R/R MM have shown a broad therapeutic window, with only modest induction of inflammatory cytokines. This correlates with a low incidence and severity of cytokine release syndrome, short cytokine release syndrome duration, and no observed ICANS events. Importantly, EMB-06 maintains potent and durable cytotoxic activity against BCMA-expressing cells, supporting an ideal target product profile that is mechanistically aligned with the therapeutic goals of autoimmune disease management.

By translating mechanistic advantages into a differentiated safety and efficacy profile compared to other BCMA-targeting TCEs and CAR-T therapies, EMB-06 is associated with notably lower cytokine release syndrome incidence and severity, shorter cytokine release syndrome duration, and sustained pharmacodynamic marker activity that may allow for less frequent dosing regimens. Achieving a unique balance of reduced immunotoxicity, favorable adverse event-related pharmacodynamic modulation, and sustained depletion of pathogenic targets supports expanding EMB-06 into autoimmune disease indications.

EMB-06 has shown encouraging progress in treating multiple autoimmune diseases. In April 2024, we received IND approval for EMB-06 for adult patients with pemphigus vulgaris and pemphigus foliaceus. Meanwhile, our collaboration partner Candid is conducting clinical trials of EMB-06 for systemic lupus erythematosus (“SLE”), generalized myasthenia gravis (“gMG”) and thyroid eye disease (“TED”) in China. It has also initiated investigator-initiated study (“IIT”) for EMB-06 targeting refractory seropositive rheumatoid arthritis (“RA”) in China. Candid’s activities in China are limited to clinical trials for the purposes of obtaining regulatory approval in the Candid Territory. See “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06” for more details.

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- Industrial scalability. EMB-06 demonstrates exceptional industrial scalability, attributed to our FIT-Ig platform, which enhances manufacturing efficiency through high protein expression levels and superior recovery rates. Our FIT-Ig platform is designed with a native-like architecture, eliminating the need for synthetic linkers or sequence modifications. This streamlined structure not only improves production robustness but also ensures consistency in product quality. Its symmetrical, IgG-based design enables precise assembly of three component chains without requiring mutations or peptide linkers. As a result, EMB-06 can be efficiently expressed in mammalian cells at high yields and purified to homogeneity using standard protocols, minimizing the need for extensive process optimization.

The FIT-Ig platform has been validated for scalability and efficiency in manufacturing EMB-06. At a 200 L batch scale, stable CHO cell lines consistently achieve titers of ~4 g/L, while the total purification recovery rate is ~50%. Furthermore, the platform incorporates a robust strategy for generating high-performing CHO cell clones, enabling seamless scalability from 200 L to 1000 L bioreactor systems without compromising yield or quality. These capabilities ensured EMB-06’s suitability for efficient, cost-effective, and large-scale production, meeting the demands of industrial biopharmaceutical manufacturing.

Summary of Clinical Trial Results

Phase I/II trial of EMB-06 for R/R MM

With regulatory clearance in Australia in March 2021 and IND approval from the NMPA in July 2021, we launched the Phase I/II trial of EMB-06 in patients with R/R MM in May and July 2021 in Australia and China, respectively, and completed the dose-escalation Phase I portion of this trial in August 2024. We were the sponsor of this clinical trial.

Trial design. This trial is a first-in-human, Phase I/II, open-label study of EMB-06 in patients with R/R MM and was designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of EMB-06. Both Phase I and Phase II trials were planned to include a screening period (Day -28 to Day -1), a step-up dosing period (only for 2 mg and above dose groups, Cycle 0, 7 days or longer), a treatment period (28 days per cycle) and a safety follow-up period (30 days after the last dose). Phase II was also planned to include a survival follow-up period (every 12 weeks after the last dose until death or the data cutoff date of the study).

Eligible patients are those who have R/R MM and have received at least two prior lines of therapy (three or more for patients in the United States). These prior therapies must include a proteasome inhibitor (PI), an immunomodulatory drug (IMiD), and, if accessible, an anti-CD38 antibody. Patients must also have measurable MM. Additionally, individuals who have previously received BCMA-targeted therapy are not eligible, with the exception that up to 10 patients in Phase II of the trial may have had prior exposure to BCMA-targeted treatments.

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The primary objective of the Phase I study was to assess the safety and tolerability of EMB-06 and determine the MTD and/or RP2D. Secondary objectives included characterizing the PK of EMB-06, evaluating its immunogenicity, and assessing its preliminary antitumor activity. Exploratory objectives involved investigating the relationship between EMB-06 and cytokine release, pharmacodynamic biomarkers, predictive biomarkers related to efficacy, and the exposure-response relationship. The primary endpoints focused on safety, including the incidence and severity of adverse events, dose-limiting toxicity, and tolerability measures such as dose interruptions and intensity. Secondary endpoints included PK parameters, immunogenicity, and preliminary efficacy outcomes. Exploratory endpoints encompassed biomarkers of cytokine release, pharmacodynamics, predictive markers like BCMA expression, and correlations between PK, biomarkers, and clinical outcomes. The study employed a step-up dosing strategy and Bayesian Optimal Interval Design to guide dose escalation in Phase I, with plans for expansion cohorts at the RP2D/MTD in Phase II.

The starting dose of EMB-06 for the Phase 1 clinical study was determined as 0.2 mg based on the minimal anticipated biological effect level (MABEL), taking into account preclinical PK data observed in cynomolgus monkeys. This starting dose is approximately 1/800 of the maximum recommended starting dose (MRSD) level under relevant guidelines of the NMPA and FDA and provided a potentially wide safety margin compared to the highest non-severely toxic dose (HNSTD) determined in preclinical studies. Additionally, while the soluble BCMA (sBCMA) in human circulatory system may neutralize the efficacy of EMB-06 by binding to it before it reaches target cells, the starting dose is considered low enough not to cause safety issues. In comparison, the starting doses of other BCMA/CD3 targeted antibodies for the first human trial exceeded or were close to the proposed starting dose of EMB-06.

The primary objective of the Phase II portion was to further evaluate the preliminary antitumor activity of EMB-06 at the established RP2D and to continue the assessment of safety and tolerability. Additional objectives included further characterization of PK and immunogenicity, exploration of PD effects and predictive biomarkers related to clinical efficacy, analysis of OS rate, and evaluation of population PK as well as the exposure-response relationship. The primary endpoints of the Phase II portion were to assess preliminary antitumor activity, safety, and tolerability. Secondary endpoints included further PK parameters, ADA incidence, and additional antitumor efficacy endpoints such as best overall response, PFS, clinical benefit rate, DOR, and time to response. Exploratory endpoints extended to analysis of PD biomarkers, predictive clinical biomarkers, overall survival, MRD negativity rate, and modeling of exposure-response relationships, including population PK parameters.

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Trial status. We completed the dose-escalation Phase I portion of this trial in August 2024 with 40 patients enrolled. As of the Latest Practicable Date, we were winding down this trial pursuant to our relevant license and collaboration agreement with Candid. See “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06” for more details.

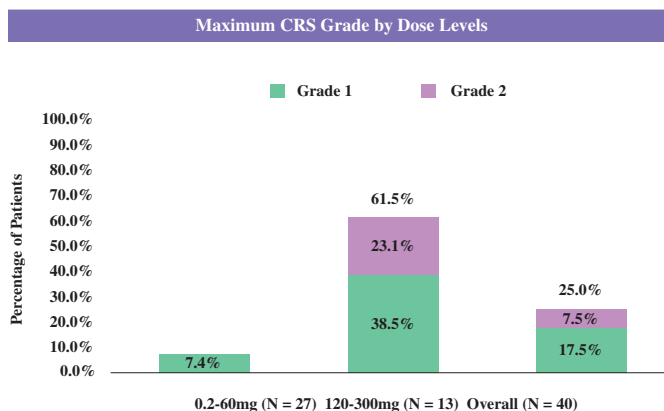
Safety results. As of December 30, 2024, a total of 40 subjects had received EMB-06 across dose levels ranging from 0.2 mg to 300 mg, including three subjects in the 0.2 mg group, three in the 0.6 mg group, four in the 2 mg group, four in the 6 mg group, four in the 15 mg group, four in the 30 mg group, five in the 60 mg group, 4 in the 120 mg group, four in the 200 mg group, and five in the 300 mg group. As of the same cut-off date, dose-limiting toxicity was observed in only one subject in the 60 mg group. The reported dose-limiting toxicities, by preferred term, included Grade ≥ 3 cardiac failure, abnormal hepatic function, viral pneumonia, and increased blood creatinine.

The following table summarizes the safety results of the trial:

Infections ($\geq 5\%$), n (%)	N = 40	
	All Grades	Grade ≥ 3
Patients with ≥ 1 infection, n (%)	28 (70.0)	15 (37.5)
Pneumonia	11 (27.5)	8 (20.0)
Upper respiratory tract infection	10 (25.0)	2 (5.0)
COVID-19	7 (17.5)	2 (5.0)
Respiratory tract infection	6 (15.0)	1 (2.5)
Urinary tract infection	5 (12.5)	0
Opportunistic infection ^a	3 (7.5)	1 (2.5)
Tuberculosis	1 (2.5)	0
Hepatitis B reactivation	1 (2.5)	0
Pneumonia fungal	1 (2.5)	1 (2.5)
Conjunctivitis	3 (7.5)	0
Bronchitis	2 (5.0)	0
Lower respiratory tract infection	2 (5.0)	1 (2.5)
Viral upper respiratory tract infection	2 (5.0)	0

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N = 40	
Patients with CRS, n (%)	10 (25.0)
Median onset (range), days ^c	1 (1-2)
Median duration (range), days ^c	3 (1-6)
Occurrence of CRS, n/m ^a	
Step-up dose 1	2/34 (5.9)
Step-up dose 2	0/4
First full dose	8/39 (20.5)
Subsequent full dose	3/38 (7.9)
Number of occurrences	
1 occurrence	7/10 (70.0)
2 occurrence	3/10 (30.0)
Patients with supportive measure to treat CRS	
Oxygen	1/10 (10.0)
Tocilizumab	2/10 (20.0)
Steroids or Vasopressor	0

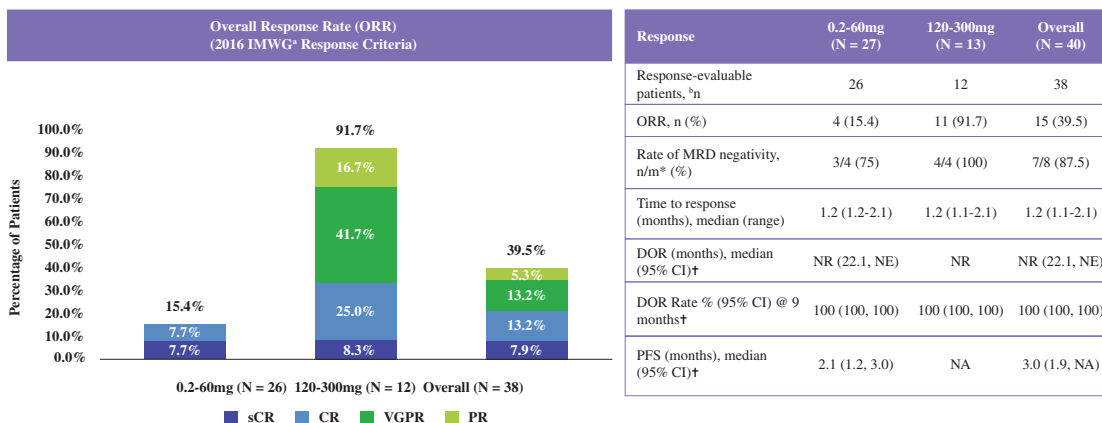


^am = Only subjects who had corresponding dose given are counted. ^bAssessed per ASTCT criteria. ^cbased on CRS occurrences.

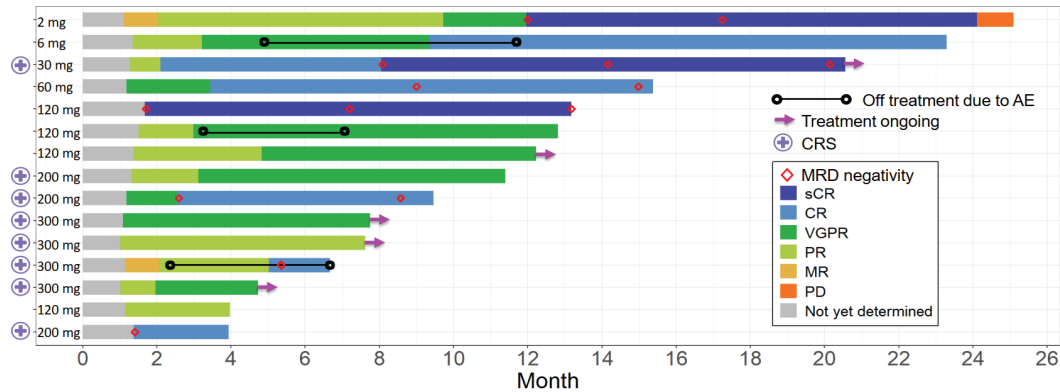
Source: Company data

Efficacy results. As of December 30, 2024, 38 subjects had at least one post-baseline efficacy evaluation. Among response-evaluable patients, the ORR was 91.7% (11/12) in the 120 to 300 mg dose groups and 39.5% (15/38) across all dose groups. Specifically, three subjects (7.9%) achieved stringent complete response, five subjects (13.2%) achieved complete response, five subjects (13.2%) achieved very good partial response, and two subjects (5.3%) achieved PR. In particular, an ORR of 100.0% was observed at the 120 mg dose level, with no occurrences of cytokine release syndrome. The median DOR was not reached, with only one patient experiencing progressive disease after a DOR of 22.1 months. Notably, patients who experienced treatment delays of ≥ 3 months due to adverse events still demonstrated sustained responses in one case and deepened responses in two cases (from very good partial response to complete response and from partial response to complete response, respectively).

The following charts summarize selected efficacy data of the trial:



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Source: Company data

Conclusion. EMB-06 demonstrated a favorable safety profile, with the MTD not reached. The treatment was associated with relatively low hematologic toxicity and a 25% incidence of cytokine release syndrome, all of which were Grade 1/2, transient, and manageable. Importantly, no case of ICANS was reported. Pharmacokinetically, EMB-06 exhibited a dose-proportional profile with low immunogenicity. At higher dose levels (120 mg to 300 mg), the study reported a 91.7% ORR, higher than teclistamab (63.0%) and elranatamab (61.0%) according to their published clinical data, including a 33.3% complete response or above rate. Responses were durable, with a 100% DOR rate at 9 months, and deep, as evidenced by a negative minimal residual disease rate of 100.0% in the 120 to 300 mg dose groups and 87.5% across all dose groups.

Additionally, a robust change in PD markers, such as reductions in CD19-positive B-cell populations and IgG levels, was observed in responders. These results strongly support the further investigation of EMB-06 in B-cell- and plasma-cell-related autoimmune diseases.

Phase Ib study of EMB-06 for pemphigus in China

Trial design. This trial is a randomized, double-blind, placebo-controlled Phase Ib study to evaluate the pharmacokinetics, pharmacodynamics, safety, and tolerability of EMB-06 in adult patients with pemphigus (vulgaris or foliaceus) in China. The trial aims to assess the safety and tolerability of intravenous EMB-06, with the primary endpoint being the incidence and severity of adverse events, changes in safety parameters, as well as dose interruptions and intensity. Secondary objectives include determining the PK profile, evaluating immunogenicity and preliminary efficacy, proposing initial dosing regimens, and assessing the impact on Dsg1/3 antibody titers, which are clinically important because reductions in these autoantibodies may indicate improved disease control and reduced autoimmune activity in patients. Corresponding secondary endpoints are PK parameters, incidence and titer of anti-drug antibodies, changes in pemphigus disease area index scores and investigator global assessment which reflect disease severity and overall clinical improvement for the patient, and percentage reduction of Dsg1/3 antibodies from baseline. Exploratory objectives and endpoints focus on the pharmacodynamic effects of selected blood biomarkers, the relationship between EMB-06 exposure and cytokine release, and the exposure-response relationship, including changes in IgG, soluble BCMA, lymphocyte subsets, cytokine profiles, and the association between PK/PD markers and efficacy or safety outcomes.

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Trial status. We submitted the IND application to the NMPA in February 2024 and received approval in April 2024. Patient enrollment is planned to commence when Candid achieves the predefined milestone, in accordance with certain license and collaboration agreement with Candid for EMB-06. For more details, see “Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06.”

Clinical Development Plan

BCMA-targeted TCEs present a novel approach in autoimmune disease treatment. BCMA is commonly found on plasma cells and can also be found on B cells. B cells and plasma cells play a central role in autoimmune disease pathogenesis by contributing to the generation of pathogenic autoantibodies and immune dysregulation. Targeting BCMA can be an effective approach for depleting pathogenic plasma cells, offering therapeutic potential for diseases like systemic sclerosis, Sjogren’s syndrome, idiopathic inflammatory myositis and rheumatoid arthritis. Leveraging our clinical experience and data-driven insights from EMB-06 in relapsed or refractory MM, we intend to expand its evaluation into autoimmune indications. For oncology indications, we are wrapping up the Phase I portion of our ongoing multi-center Phase I/II clinical trial of EMB-06 in accordance with the wind-down plan defined in the agreement, and we do not expect to pursue further development of EMB-06 in oncology in the near term, but rather in autoimmune indications.

Under the EMB-06 License and Collaboration Agreement, we retain exclusive rights to develop, register, manufacture and commercialize EMB-06 in the EpimAb Territory. Therefore, we will be responsible at our own cost for all pivotal-stage clinical development, NMPA filings to eventually become sole marketing authorization holder in China and commercialize EMB-06. Our initiation of clinical trials for EMB-06 in China is contingent upon Candid’s commencement of the first pivotal clinical trial in the Candid Territory. This sequence of events was intentionally negotiated by the parties to align global developments and avoid duplicate clinical studies. Once Candid initiates its pivotal clinical trial, we expect to utilize the data package generated by Candid in its clinical Phase I and Phase II trials for our own clinical development in China, to reduce scientific and operational uncertainty as well as cost. We then may run our own independent pivotal trial in China or participate in a global trial program initiated by Candid, to the extent appropriate under the protocol and to commence our development program for autoantibody-related autoimmune diseases in China. We and Candid maintain a joint steering committee to oversee the development of EMB-06, through which we have visibility into and oversight of the global development plan. We retain decision-making authority over development, manufacturing and commercialization of EMB-06 in the EpimAb Territory.

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As of the Latest Practicable Date, Candid is conducting early clinical activities in China. Under the EMB-06 License and Collaboration Agreement, Candid may, at its own discretion and at its sole cost, conduct early-stage clinical studies in China for the purpose of accelerating data generation for its global development plan. Based on publicly available clinical trial registry information, the IND approvals obtained by Candid cover Phase Ib, open-label, multicenter studies evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary clinical activity of EMB-06 in patients with systemic SLE lupus and gMG. Based on publicly available clinical trial registry information, these studies commenced in the third quarter of 2025 and have estimated primary completion dates in the fourth quarter of 2027. In addition, certain investigator-initiated studies are expected to reach primary completion by the fourth quarter of 2026. No pivotal or registration-enabling studies have been or will be initiated by Candid in China, Candid’s early-stage studies are not mandated by regulatory authorities in the Candid Territory; rather, as advised by Frost & Sullivan, they reflect a strategic decision to improve patient enrollment efficiency, accelerate early safety and PK/PD readouts and shorten overall global development timelines.

Candid’s clinical activities in the EpimAb Territory do not affect (i) our exclusive rights to develop, manufacture, register, own the marketing authorization for, and commercialize EMB-06 in the EpimAb Territory; (ii) the financial payment obligations of Candid under the EMB-06 License and Collaboration Agreement, including milestone and royalty payments, which are triggered solely by development, regulatory and commercial events in the Candid Territory; (iii) any patents or patent rights granted under the EMB-06 License and Collaboration Agreement; or (iv) Candid’s exclusive rights to conduct pivotal trials, own marketing authorizations for, or commercialize EMB-06 in the Candid Territory. As of the Latest Practicable Date, we had received an upfront payment of US\$30.0 million under the EMB-06 License and Collaboration Agreement, and no milestone payments had been triggered, nor are any milestone payments payable, by Candid’s clinical activities in the EpimAb Territory. For further details, see “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06.”

We consider EMB-06 to be one of our key products notwithstanding the winding down of the current clinical trial in patients with relapsed/refractory multiple myeloma, given its differentiated mechanism of action, market potential, and strategic importance to our near-term development focus in high-value autoimmune disease indications. The decision to wind down the oncology trial was made to avoid any potential impact on Candid’s conduct of clinical trials of EMB-06 in autoimmune indications and its future regulatory submissions in the Candid Territory, and was not based on safety or efficacy concerns. This approach enables both parties to pursue their respective development strategies without duplicative or conflicting clinical activities. Under our EMB-06 License and Collaboration Agreement with Candid, our initiation of clinical trials for EMB-06 is contingent upon Candid’s initiation of its pivotal clinical trial intended to enable the preparation and filing of marketing authorization application in the Candid Territory. This sequencing reflects a structured and commercially reasonable risk-management arrangement between the parties, rather than a technical constraint on our ability to develop EMB-06 in China. Despite the interim pause, we have established operational readiness to rapidly initiate bridging studies and Phase III pivotal trials in autoantibody-related

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autoimmune diseases in alignment with Candid’s program. See “Future Plans and Use of [REDACTED]” for more details. EMB-06 is therefore positioned to expand our therapeutic focus beyond oncology into immunology, diversifying our pipeline and enhancing our long-term commercial potential. Its designation as a key product reflects both its clinical promise and its strategic role in our portfolio, as well as our expectation that, upon resumption of development, it will generate meaningful value for stakeholders.

License, Rights and Obligations

Pursuant to the EMB-06 License and Collaboration Agreement, we granted Candid an exclusive, royalty-bearing and sublicensable license under our applicable controlled patents and know-how to research, develop, manufacture and commercialize EMB-06 and certain derivatives of EMB-06 that are BCMA/CD3 bispecific antibodies for the diagnosis, treatment or prevention of all human and non-human diseases outside China (including Hong Kong, Macau and Taiwan). For more details, see “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06” in this section.

Material Communications with Competent Authorities

We submitted clinical trial notification (“CTN”) to the TGA of Australia in March 2021 to conduct the Phase I/II clinical trial for EMB-06 in patients with R/R MM and received the TGA’s acknowledgment in the same month. Together with the approval from applicable human research ethics committee (“HREC”) for this trial in January 2021, we secured all necessary regulatory clearance for the Phase I/II clinical trial for EMB-06 in R/R MM in Australia upon the TGA acknowledgement under the CTN scheme. We further submitted the IND applications for this trial to the FDA and NMPA in June 2021 and received the corresponding IND approvals in July 2021. These regulatory clearances across China, the United States and Australia enable us to evaluate EMB-06 in diverse patient populations and generate globally relevant clinical data to support its further development. As we expand the indication of EMB-06 into autoimmune diseases, we submitted the IND application for Phase Ib trial in adult patients with pemphigus vulgaris and pemphigus foliaceus to the NMPA in February 2024 and received the IND approval in April 2024. Meanwhile, Candid, our collaboration partner, obtained the implied IND approval for EMB-06 from the NMPA in SLE and gMG in June 2025, and in TED in October 2025. Candid’s activities in China are limited to clinical trials for the purposes of obtaining regulatory approval in the Candid Territory. See “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06” for more details.

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The following table sets forth a summary of material communications with regulatory authorities regarding EMB-06:

Milestone/Stage	Timeline
HREC approval (Phase I/II clinical trial for the treatment of R/R MM)	January 2021
Submission of clinical trial notification (Phase I/II clinical trial for the treatment of R/R MM) to the TGA	March 2021
Acknowledgement (Phase I/II clinical trial for the treatment of R/R MM) from the TGA	March 2021
Submission of IND application (Phase I/II clinical trial for the treatment of R/R MM) to the FDA	June 2021
IND approval (Phase I/II clinical trial for the treatment of R/R MM) from the FDA	July 2021
Submission of IND application (Phase I/II clinical trial for the treatment of R/R MM) to the NMPA	June 2021
IND approval (Phase I/II clinical trial for the treatment of R/R MM) from the NMPA	July 2021
Submission of IND application (Phase Ib clinical trial for the treatment of adult patients with pemphigus vulgaris and pemphigus foliaceus) to the NMPA	February 2024
IND approval (Phase Ib clinical trial for the treatment of adult patients with pemphigus vulgaris and pemphigus foliaceus) from the NMPA	April 2024
Implied IND approval (Phase I clinical trial for SLE and gMG) from the NMPA*	June 2025
Implied IND approval (Phase I clinical trial for TED) from the NMPA*	October 2025

Note:

* Obtained by Candid

As of the Latest Practicable Date, we had not received any regulatory agency’s concerns or objections to our clinical development plans.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EMB-06 SUCCESSFULLY.

EMB-07 (ROR1/CD3), Our Key Product

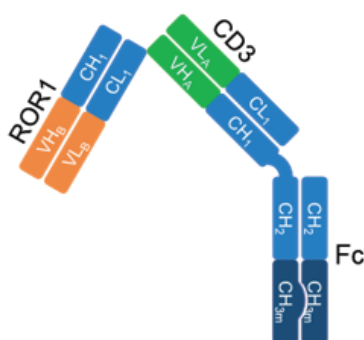
EMB-07 is a bispecific TCE designed to target ROR1 and CD3, offering a therapeutic approach for the treatment of both solid tumors and hematologic malignancies. This molecule features a unique antibody structure, comprising two distinct Fab fragments directly connected in a crisscross orientation without using any peptide linker or mutation. The humanized anti-ROR1 light chain is directly linked to the N-terminus of the anti-CD3 heavy chain, thereby ensuring precise assembly and avoiding light chain mispairing.

To optimize its therapeutic potential, EMB-07 incorporates critical structural modifications. The Fc fragment employs a “knob-into-hole” design combined with two specific mutations, Leu234Ala and Leu235Ala, which effectively abolishes antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity while preserving FcRn binding. These adaptations minimize Fc-mediated effector functions, enhancing the molecule’s safety and efficacy profile.

EMB-07 exerts its antitumor activity by simultaneously binding to ROR1-expressing tumor cells and CD3-expressing T cells. This dual engagement facilitates the recruitment of T cells to the tumor cells, where they become activated and execute targeted tumor cell killing. By leveraging this mechanism, EMB-07 has the potential to be developed as a treatment for cancers where current therapeutic options remain limited.

Drug Design and Mechanism of Action

The molecular structure of EMB-07 is illustrated below:



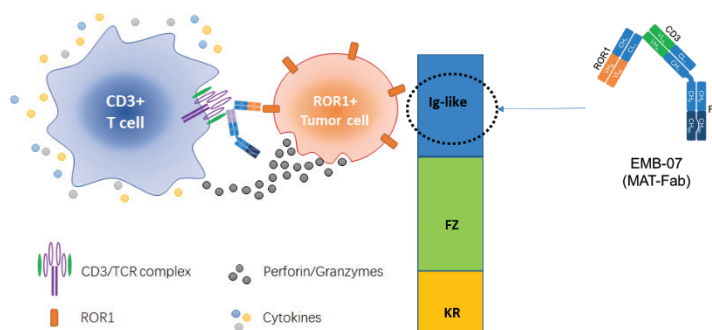
**EMB-07
(MAT-Fab)**

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EMB-07 exerts its therapeutic effects through a highly specific mechanism of action, leveraging the unique molecular structure of the ROR1 protein. ROR1, a transmembrane protein, plays a critical role in the progression of several cancers, including solid tumors and lymphomas. EMB-07 is designed to specifically target the Ig-like domain of ROR1 with high affinity, while exhibiting relatively low affinity for CD3 on T cells.

EMB-07’s bispecific structure allows it to simultaneously bind to ROR1 on tumor cells and CD3 on T cells. Through this dual engagement, the T cells mediate potent and precise tumor cell killing, offering a targeted and efficient approach to addressing cancers characterized by ROR1 overexpression. Meanwhile, EMB-07 induces limited cytokine release during tumor cell killing. This mechanism underscores EMB-07’s potential to provide a highly selective and effective treatment for malignancies where current therapeutic options remain limited.

The following diagram illustrates the mechanism of action of EMB-07:



Market Opportunities and Competition

DLBCL

DLBCL is the most prevalent form of aggressive non-Hodgkin lymphoma, accounting for approximately 30-40% of non-Hodgkin lymphoma cases globally. The disease is characterized by rapid progression and high proliferative potential, necessitating immediate therapeutic intervention. Despite advancements in treatment, R/R DLBCL remains a significant challenge, with limited options for patients who fail frontline therapy. The global DLBCL market is driven by increasing incidence rates, advancements in immunotherapy, and the growing adoption of targeted therapies. The DLBCL drug market in China has experienced expansion, growing from US\$0.5 billion in 2020 to US\$1.3 billion in 2024, with a CAGR of 25.1% with an anticipated increase to US\$3.3 billion by 2030 with a CAGR of 16.6% from 2024 to 2030 and further reach US\$5.1 billion by 2034, indicating a CAGR of 11.8% from 2030 to 2034. Globally, the DLBCL drug market reached US\$9.5 billion in 2024, up from US\$6.3 billion in 2020 representing a CAGR of 10.5%, and is forecasted to grow to US\$20.3 billion in 2030, indicating a CAGR of 13.5% and further reach US\$27.2 billion in 2034, with a CAGR of 7.7% from 2030 to 2034.

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The current standard of care includes R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone), which achieves curative intent in 60-65% of patients. However, nearly one-third of patients relapse or present with primary refractory disease, leading to poor prognosis and high mortality rates. Despite the availability of these therapies, several challenges remain. High relapse rates continue to be a critical issue, with many patients failing to achieve long-term remission despite initial chemosensitivity. Disease heterogeneity, both molecular and clinical, leads to variable responses and resistance mechanisms that complicate treatment selection. Additionally, the lack of biomarker-driven therapies limits personalized medicine approaches, preventing optimal patient-specific treatment planning. Finally, while combination therapies have potential to improve outcomes, optimal regimens remain undefined, and balancing efficacy with toxicity remains an ongoing challenge.

ROR1 is selectively expressed in aggressive DLBCL subtypes, including those resistant to current therapies. Unlike traditional CD20-targeting monoclonal antibodies, which rely on antibody-dependent cytotoxic mechanisms, ROR1/CD3 TCEs provide an alternative mechanism for direct tumor suppression, reducing immune evasion and resistance. By linking CD3-positive T cells to ROR1-expressing malignant B cells, ROR1/CD3 TCE therapies initiate a potent immune-mediated cytotoxic response, effectively bypassing resistance pathways associated with conventional antibody therapies. Furthermore, ROR1/CD3 may be integrated into combination regimens to enhance efficacy and reduce the likelihood of developing treatment-resistant disease. For patients intolerant to intensive chemotherapy, ROR1/CD3 provides a viable option within chemo-free or chemo-light treatment settings, broadening accessibility to effective immunotherapies.

Unlike CAR-T cell therapies, which require patient-specific genetic modification, ROR1/CD3 TCEs function as allogeneic, off-the-shelf treatments, ensuring rapid availability and eliminating logistical barriers associated with personalized manufacturing. Additionally, bispecific antibody production incurs lower manufacturing costs compared to CAR-T therapies, making ROR1/CD3 TCE a financially viable alternative for broader adoption in both frontline and relapsed settings.

The pharmacokinetic profile of ROR1/CD3 TCEs resembles that of monoclonal biologics, ensuring predictable dosing, consistent drug behavior, and streamlined administration — including potential subcutaneous delivery. This familiarity enhances physician adoption while maintaining robust immune engagement against ROR1-expressing DLBCL cells. As an immediate-use therapy, ROR1/CD3 TCEs offer a scalable, cost-efficient solution to address unmet needs in DLBCL treatment.

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As of the Latest Practicable Date, there was no marketed ROR1/CD3 TCE for the treatment of lymphoma globally. EMB-07 remains the only clinical-stage ROR1/CD3 bispecific antibody candidate for the treatment of lymphoma in China as of the Latest Practicable Date. The following chart sets forth the selected information of all ROR1/CD3 bispecific antibody candidates for the treatment of lymphoma globally and in China:

Global and China Pipelines									
Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-07	Our Company	ROR1/CD3	Bispecific Antibody	Lymphoma	I	Mono	Second-line/ Third-line/ Last-line	2022/11/03	China, Australia
NVG-111	NovalGen	ROR1/CD3	Bispecific Antibody	Lymphoma	I/II	Mono	Second-line/ Third-line/ Last-line	2020/07/31	UK

Source: NMPA, CDE, Frost & Sullivan

Solid tumors

The global incidence of cancers has been growing with total global cancer incidence increased from 18.5 million in 2019 to 21.3 million in 2024, among which 17.3 million and 20.0 million were solid tumors in 2019 and 2024, respectively. The numbers are expected to grow to 26.6 million and 24.9 million, respectively, in 2034. Despite the significant number of global solid tumor cases, current treatment options for many types of solid tumors, such as gastric cancer and pancreatic cancer, remain limited in efficacy and cannot benefit a broad range of cancer patients. This unmet medical need represents a significant market opportunity and is expected to drive the growth of innovative therapeutic solutions.

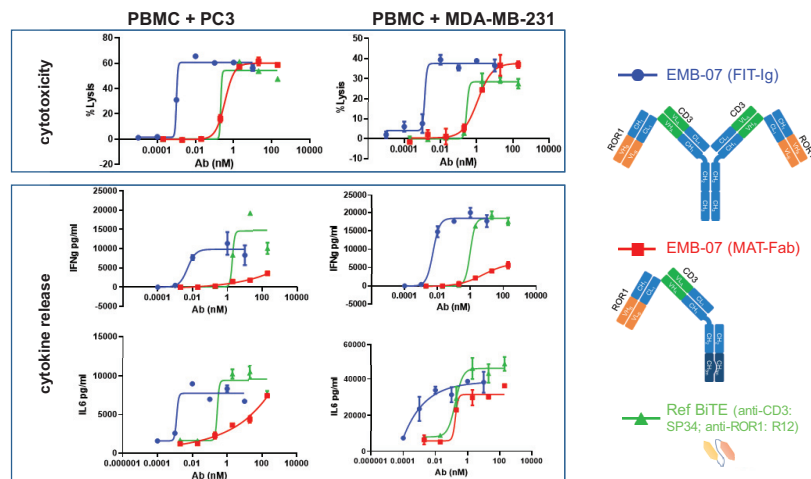
CD3 bispecific antibodies have shown promise as an immunotherapeutic approach for solid tumors by redirecting T cells regardless of TCR specificity and enabling effective tumor cell killing. While several CD3-BsAbs have achieved clinical success in hematologic malignancies, there is increasing interest and ongoing efforts to expand their indications to solid tumors. Furthermore, ROR1, which is overexpressed in various solid tumors including small cell lung cancer, has emerged as a promising therapeutic target. Novel agents targeting ROR1, such as dual antibodies, have the potential to address the significant unmet needs in the solid tumor field. As clinical development progresses, we plan to further define the most suitable indications for our ROR1/CD3 bispecific antibody based on emerging clinical data, with the aim of maximizing patient benefit in solid tumors.

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Competitive Advantages

- Optimized 1+1 structure enabling strong antitumor activity. EMB-07 leverages an optimized structural design tailored to overcome key challenges associated with its target and resistance mechanisms. By addressing these obstacles, EMB-07 demonstrates robust antitumor activity, as evidenced by extensive preclinical evaluations. The 1+1 MAT-Fab format of EMB-07 was selected after rigorous comparison with the 2+2 FIT-Ig format in preclinical studies. Results showed that the MAT-Fab configuration achieved comparable tumor cell killing efficacy while significantly reducing cytokine release. Additionally, it exhibited a superior pharmacokinetic profile in cynomolgus monkeys, underscoring its potential for improved therapeutic performance.

Moreover, EMB-07 was benchmarked against a competitor molecule utilizing a different 1+1 BiTE format (NVG-111). While both molecules demonstrated similar *in vitro* tumor-killing activity, EMB-07 induced substantially lower cytokine release. This reduction in cytokine-mediated toxicity positions EMB-07 as a therapeutic candidate with enhanced safety and efficacy, offering a distinct advantage in the field of cancer immunotherapy.



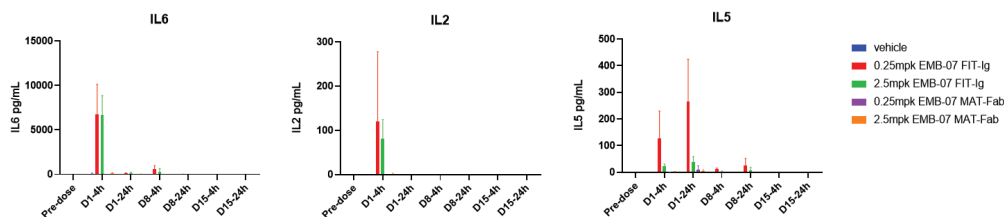
Source: Company data

- Striking the balance between safety and efficacy. The preclinical data for EMB-07 highlight its potential to deliver robust anti-tumor efficacy while minimizing the risk of cytokine release syndrome, a common and severe side effect associated with many immunotherapies. Comparative studies underscore EMB-07's improved safety profile, with preclinical evaluations in non-human primates demonstrating significantly reduced toxicity compared to the FIT-Ig format, suggesting that EMB-07 is uniquely positioned to provide a more favorable therapeutic window, achieving a critical balance between potent anti-tumor activity and patient safety.

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- Extended half-life for sustained therapeutic exposure compared to other clinical-stage ROR1 TCEs. EMB-07 exhibits an advantage in half-life in monkeys, maintaining prolonged drug exposure with half-life values ranging from 38.5 to 125.8 hours, suggesting extended systemic persistence and the potential for less frequent dosing while ensuring sustained therapeutic levels.

EMB-07 MAT-Fab Induced Very Low Cytokine Release in Cynomolgus Monkeys



Summary of Clinical Trial Results

Ongoing Phase I clinical trial of EMB-07 monotherapy for solid tumors and R/R lymphomas

We initiated the first-in-human Phase I study of EMB-07 in patients with solid tumors in Australia and China in January 2023. The study was initially designed to target solid tumors, with ethics committee approval received in September 2022 and acknowledgment from the TGA in Australia in October 2022, as well as IND approval from the NMPA in China in January 2023. We later expanded the indication of this study to include R/R lymphoma. For the expanded indication, we received ethics committee approval and acknowledgment from the TGA in Australia both in July 2023, as well as IND approval from the NMPA in China in May 2023. Following these approvals, the study proceeded to evaluate the safety and efficacy of EMB-07 in patients with both solid tumors and R/R lymphomas.

Trial design. This is a first-in-human, open-label, Phase I, multicenter dose escalation study to identify the RP2D and to evaluate the safety, tolerability, pharmacokinetics, and antitumor activities of EMB-07 in adult patients with advanced solid tumors or R/R lymphomas.

The primary objective of the trial is to evaluate the safety and tolerability of EMB-07 intravenously and to determine the MTD and/or RP2D. The secondary objective is to characterize the pharmacokinetics of EMB-07, assess its immunogenicity, and evaluate its preliminary antitumor activities. Exploratory objectives include investigating the pharmacodynamic relationships between pharmacokinetics, pharmacodynamics, adverse event profiles, and clinical activity, as well as evaluating predictive peripheral/tumor biomarkers related to EMB-07's efficacy. The primary endpoints are the incidence and severity of adverse events, tolerability, and the incidence of dose-limiting toxicities. Secondary endpoints include

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pharmacokinetic parameters, anti-drug antibody incidence and titer, and preliminary antitumor activity metrics. Exploratory endpoints involve pharmacodynamic biomarkers, cytokine release, predictive biomarkers, and the association of PK/PD with efficacy and safety endpoints.

Trial status. As of May 20, 2025, the lymphoma portion has completed dosing at 12 mg cohort. A total of 27 patients with lymphomas have been enrolled. The solid tumor part has enrolled 25 patients at doses up to the 25 mg cohort.

Efficacy results. As of ongoing medical review in May 2025, preliminary antitumor activity was observed in the 6 mg dose group of the lymphoma portion, consisting of two DLBCL patients and one patient with marginal zone lymphoma experiencing histological transformation to DLBCL. All three patients had received at least three prior lines of treatment and had an International Prognostic Index (IPI) score of ≥ 2 . Among them, one achieved a partial response lasting for three months; one achieved a partial response lasting for eight months and remains on treatment; one achieved a complete response lasting for eight months and was currently under survival follow-up. These findings provide early clinical evidence supporting the efficacy of EMB-07 in lymphoma.

Ongoing Phase I/II clinical trial of EMB-07 in combination with standard of care treatments for DLBCL

We obtained IND approval from the NMPA for the Phase I/II EMB-07 in combination with standard of care regimens for patients with DLBCL in September 2025. EMB-07 is evaluated under multiple combination regimens in this platform trial, including (i) EMB-07 with R-CHOP (rituximab, cyclophosphamide, vincristine, doxorubicin, and prednisone) as a first-line treatment, as well as several second-line regimens including (ii) EMB-07 with R-GemOx (rituximab, gemcitabine, and oxaliplatin), (iii) EMB-07 with rituximab and polatuzumab (chemo-free), (iv) EMB-07 with rituximab, lenalidomide, and zanubrutinib (chemo-free), and (v) EMB-07 with rituximab and tucidinostat. We expect to initiate this trial in the second quarter of 2026.

Trial design. This is an open-label, multicenter, Phase I/II study evaluating EMB-07 in combination regimens for adult patients with aggressive B-cell non-Hodgkin's lymphoma ("B-NHL") including DLBCL, and other B-NHL which may benefit from EMB-07 combination therapies. The study includes a Phase I dose-escalation stage followed by Phase II dose-expansion across predefined cohorts in relapsed/refractory disease and in newly diagnosed settings. Approximately up to 115 participants will be enrolled.

The primary objective of the trial is to evaluate the safety and tolerability of EMB-07 based combinations and to determine the MTD and/or recommended Phase II combination dose ("RP2CD"). The secondary objectives are to characterize the pharmacokinetics of EMB-07 in combinations, assess its immunogenicity, and evaluate preliminary antitumor activity. Exploratory objectives include evaluating pharmacodynamic markers, exploring predictive biomarkers such as ROR1 expression, and assessing exposure-response relationships across pharmacodynamics, efficacy, and safety. The primary endpoints are the incidence and severity

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of adverse events, tolerability (including dose interruptions and dose intensity), and the incidence of dose-limiting toxicities. Secondary endpoints include pharmacokinetic parameters, anti-drug antibody incidence and titer, and preliminary antitumor activity measures, including overall and complete response rates and time-to-event metrics per Lugano criteria. Exploratory endpoints encompass T-cell immunophenotyping, cytokine assessments, predictive biomarker analyses, and associations of pharmacokinetic and pharmacodynamic measures with efficacy and safety outcomes.

Trial status. We submitted the IND submission to the NMPA in July 2025 and have obtained the IND approval from the NMPA in September 2025. We expect to initiate the trial in the second quarter of 2026.

Clinical Development Plan

EMB-07 monotherapy in the third-line or above DLBCL

We initiated the first-in-human Phase I study of EMB-07 in Australia in January 2023 and in China in May 2023, respectively, with preliminary efficacy signals observed in lymphoma during the dose escalation phase. Following the completion of the Phase I trial and communication with regulatory agencies expected in early 2026, we may commence a Phase II trial of EMB-07 as monotherapy in patients with third-line or above DLBCL, enrolling 80-100 patients across global sites.

EMB-07 in combination with standard of care treatments in the first-line or second-line DLBCL

We have obtained IND approval from the NMPA for a Phase I/II study evaluating EMB-07 in combination with standard of care treatments for first-line or second-line DLBCL in September 2025, and expect to initiate this trial in the second quarter of 2026. Based on the clinical data observed in the Phase I and Phase II trial of EMB-07, we expect to initiate a Phase III trial of EMB-07 as combination for the treatment of first-line or second-line DLBCL patients with IND submission expected after 2027.

License, Rights and Obligations

We are developing EMB-07 in-house and own the global rights to develop and commercialize EMB-07.

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Material Communications with Competent Authorities

We first secured regulatory clearances for EMB-07 in solid tumors and subsequently expanded its indication into R/R lymphoma. In Australia, we obtained HREC approval for EMB-07 in solid tumors in September 2022, submitted the clinical trial notification to the TGA in October 2022 and obtained its acknowledgment in the same month. With HREC approval and TGA acknowledgement, we secured all necessary regulatory clearance for EMB-07 in solid tumors in Australia under the CTN scheme. In China, we submitted IND application for EMB-07 in solid tumors to the NMPA in November 2022 and obtained the approval in January 2023.

As part of our indication expansion strategy, we extended the development of EMB-07 beyond solid tumors to include R/R lymphoma, a sizable and growing market segment where existing therapies still leave a substantial portion of patients without durable responses. Accordingly, we supplemented our IND application to the NMPA to include lymphoma in March 2023 and received corresponding approval in May 2023. In Australia, we supplemented the clinical trial notification to the TGA in July 2023 and received its acknowledgment in the same month. We also obtained HREC approval for EMB-07 in R/R lymphoma in July 2023, thereby securing all necessary regulatory clearance for EMB-07 in R/R lymphoma under the CTN scheme. In the United States, we submitted the IND approval to the FDA for both solid tumors and R/R lymphoma in March 2025 and received the approval in April 2025.

The following table sets forth a summary of material communications with regulatory authorities regarding EMB-07:

Milestone/Stage	Timeline
HREC approval (Phase I clinical trial for the treatment of solid tumors)	September 2022
Submission of clinical trial notification (Phase I clinical trial for the treatment of solid tumors) to the TGA	October 2022
Acknowledgement (Phase I clinical trial for the treatment of solid tumors) from the TGA	October 2022
Submission of IND application (Phase I clinical trial for the treatment of solid tumors) to the NMPA	November 2022
IND approval (Phase I clinical trial for the treatment of solid tumors) from the NMPA	January 2023
Supplementing IND application (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas) to the NMPA . .	March 2023

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Milestone/Stage	Timeline
IND approval (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas) from the NMPA	May 2023
HREC Approval (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas)	July 2023
Supplementing clinical trial notification (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas) to the TGA	July 2023
Acknowledgement (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas) from the TGA.	July 2023
Submission of IND application (Phase I clinical trial for the treatment of solid tumors and R/R lymphomas) to the FDA.	March 2025
IND approval (Phase I clinical trial for the treatment of R/R lymphomas) from the FDA	April 2025
Submission of IND application (Phase I/II clinical trial in combination with standard of care treatments for first-line or second-line DLBCL) to the NMPA.	July 2025
IND approval (Phase I/II clinical trial in combination with standard of care treatments for first-line or second-line DLBCL) from the NMPA.	September 2025

As of the Latest Practicable Date, we had not received any regulatory agency’s concerns or objections to our clinical development plans.

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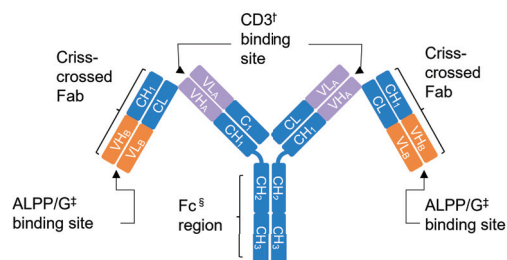
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Our Selected Preclinical Drug Candidates

EM1032 (ALPP(G)/CD3)

EM1032 is a TCE targeting the tumor-associated antigen alkaline phosphatase, placental/germ cell type (ALPP(G)). ALPP(G) is highly expressed in various solid tumors, including ovarian, endometrial, gastric cancers, and lung adenocarcinoma, while exhibiting minimal expression in normal tissues, making it a therapeutic target. EM1032 leverages our proprietary FIT-Ig platform and CD3 antibody panel to enable precise tumor targeting. Notably, EM1032 has demonstrated significant anti-tumor efficacy in preclinical studies, including against tumors that are resistant to ALPP(G)-directed ADCs. This positions EM1032 as a therapeutic option, particularly for addressing the medical need in patients with platinum-resistant ovarian cancer.

The molecular structure of EM1032 is illustrated below:



† Proprietary humanized anti-CD3 ϵ antibody

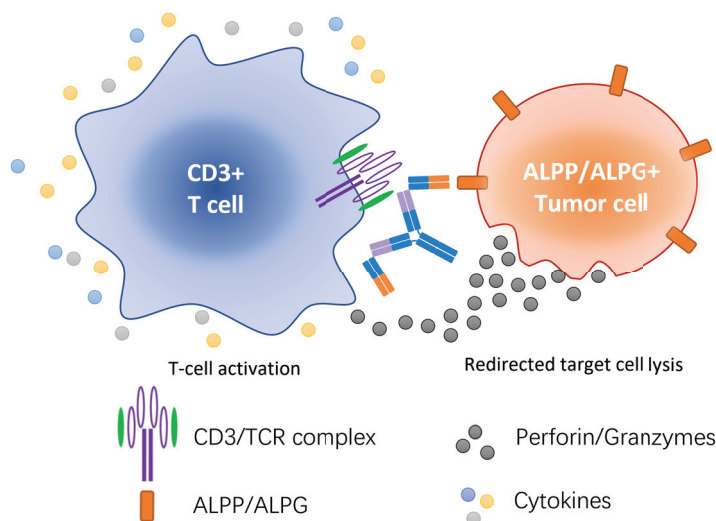
‡ Proprietary humanized antibody against both ALPP and ALPG

§ Effector function null Fc with half-life extension design

EM1032 functions as a TCE by simultaneously binding to ALPP(G) on tumor cells and CD3 on T cells. The CD3 binding activates T cells, leading to targeted tumor cell lysis while sparing normal tissues due to the restricted expression of ALPP(G) in non-cancerous tissues. By utilizing the FIT-Ig bispecific platform and proprietary CD3 antibody, EM1032 achieves IgG-like stability, fine-tuned binding affinities, and effective T-cell activation. Preclinical studies have demonstrated its ability to induce robust tumor infiltration by T cells, efficient tumor cell depletion, and ALPP(G) dependent T cells activation, resulting in highly potent anti-tumor activity even in models resistant to ALPP(G)-targeted ADCs.

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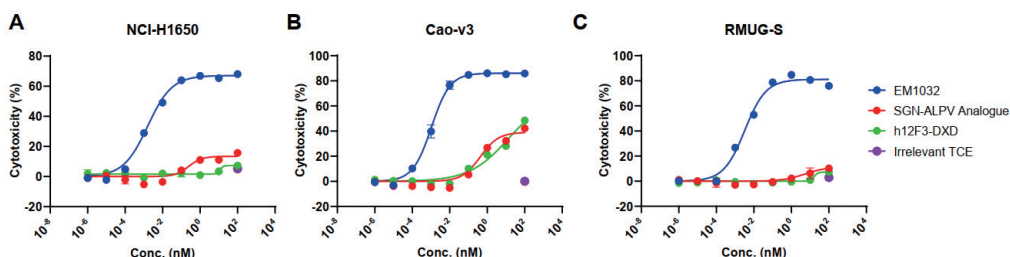
The following diagram illustrates the mechanism of action of EM1032:



EM1032 offers several distinct advantages over other investigational ALPP(G)-targeted therapies. Our proprietary FIT-Ig platform provides state-of-the-art bispecific antibody design, enabling enhanced efficacy, safety, and manufacturability. Unlike traditional autologous CAR-T approaches, EM1032’s TCE modality ensures better availability, lower manufacturing costs and potentially better safety profile by fine-tuned CD3 affinity. Furthermore, EM1032 has demonstrated preclinical efficacy in multiple ALPP(G)-positive tumor models, including in ADC-resistant ovarian cancer, and underscores its potential for the treatment of patients with platinum-resistant ovarian cancer (PROC) and its broader therapeutic applications across various epithelial solid tumors. These unique attributes position EM1032 as a candidate in the next generation of cancer immunotherapies.

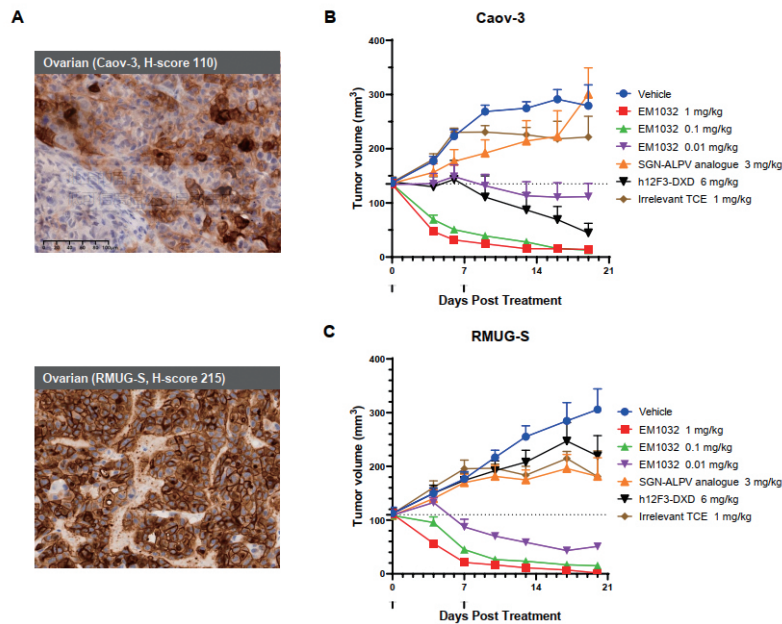
In preclinical studies, EM1032 showed potent and selective anti-tumor activity with a profile consistent with targeted T-cell engagement. *In vitro* cytotoxicity assays demonstrated higher tumor-cell killing versus reference ALPP-ADCs across multiple ALPP+ lines, including NCI-H1650 (lung), Cao-v3 (ovarian), and RMUG-S (ovarian). *In vivo*, EM1032 produced tumor growth inhibition and durable responses in ovarian cancer CDX models, including models resistant to MMAE- or DXd-based ALPP-ADCs.

EM1032 demonstrated increased *in vitro* tumor cell lysis potency than ADCs



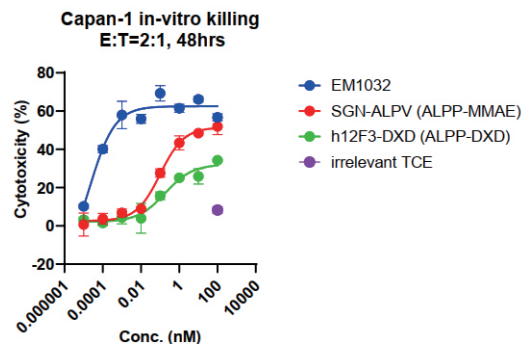
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EM1032 demonstrates notable *in vivo* anti-tumor efficacy in ADC resistant ovarian cancer models



Beyond ovarian cancer, EM1032 achieved notable efficacy in a lung cancer CDX model, where optimizing CD3 affinity further improved anti-tumor activity. Separately, in pancreatic cancer, EM1032 outperformed ALPP-ADCs in redirected killing of the KRAS-mutant Capan-1 cell line *in vitro* and enhanced tumor control when combined with the RAS(ON) inhibitor RMC6236 *in vivo*, supporting indication expansion and rational combinations. Together, these preclinical data provide a clear rationale for advancing EM1032 to clinical evaluation in PROC and other ALPP(G)-positive epithelial tumors.

Compared to ALPP ADCs, EM1032 demonstrated higher potency in redirected cytotoxicity to pancreatic cancer cell line



We expect to submit an IND application for EM1032 for the treatment of solid tumors in the first quarter of 2026.

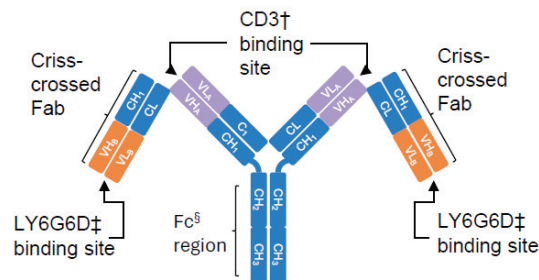
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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EM1032 SUCCESSFULLY.

EM1034 (LY6G6D/CD3)

EM1034 is a bispecific TCE targeting lymphocyte antigen 6 family member G6D (LY6G6D), a tumor-specific antigen expressed in CRC with very limited expression in normal tissues, making it an attractive therapeutic target. EM1034 demonstrates preclinical efficacy across multiple cell lines with varying LY6G6D expression levels. Additionally, it has shown limited cytokine release and low likelihood of immunogenicity, which remain subject to further clinical validation. Preclinical studies, including *in vivo* CDX models, have shown tumor eradication even at low doses. In light of these preclinical data, EM1034 is being explored as a therapeutic candidate for microsatellite stable and microsatellite instability-low CRC, where treatment options remain limited.

The molecular structure of EM1034 is illustrated below:



† Proprietary humanized anti-CD3e antibody

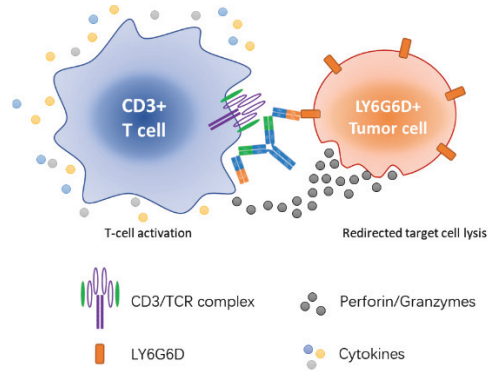
‡ Proprietary humanized antibody against LY6G6D

§ Effector function null Fc with half-life extension design

EM1034 relies on its bispecific antibody format, which enables simultaneous binding to LY6G6D on tumor cells and CD3 on T cells. This dual-targeting mechanism effectively redirects T cells to recognize and kill tumor cells. EM1034’s proprietary engineering, including its bispecific antibody format, fine-tuned CD3 affinity and clinically validated Fc modifications, ensures precise tumor targeting while minimizing off-target immune activation. By leveraging the tumor-specific expression of LY6G6D, EM1034 enhances immune-mediated tumor destruction with reduced systemic toxicity. Its cross-reactivity with cynomolgus targets further validates its potential for clinical success.

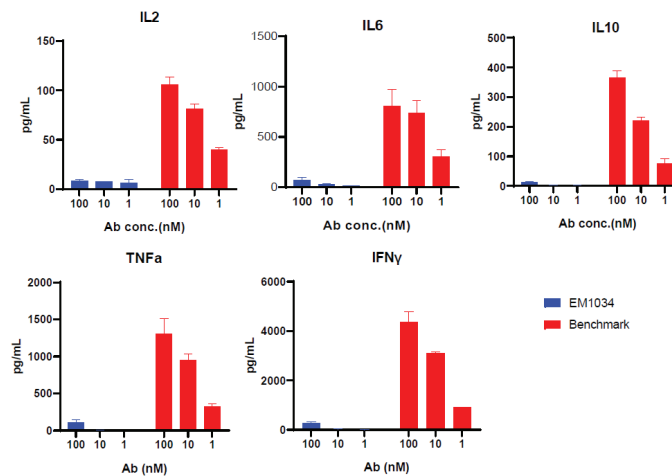
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The following diagram illustrates the mechanism of action of EM1034:



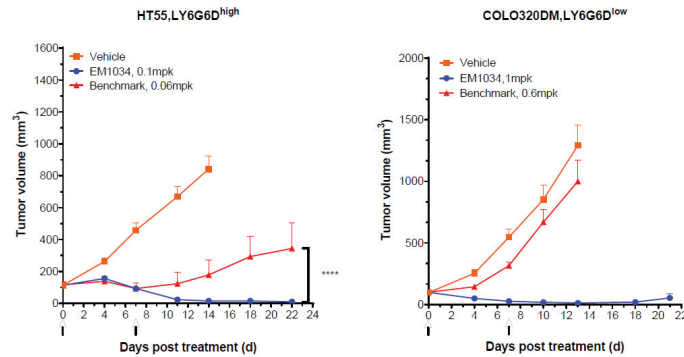
In preclinical studies, EM1034 exhibited activity with an acceptable safety profile. Compared to competitive molecules from Roche, EM1034 candidates exhibit significantly higher binding potency to LY6G6D and more effective tumor killing across all LY6G6D expression cell lines. Additionally, its minimal cytokine release potential may indicate a favorable safety profile, subject to further clinical validation. In silico analysis indicates that EM1034 has no or very low immunogenicity risk, contrasting with the high immunogenicity risks associated with Roche molecule. Furthermore, EM1034's proprietary bispecific antibody format and Fc engineering provide enhanced molecular stability and efficacy. In preclinical models, these design features have supported target engagement, collectively providing a rationale for EM1034's continued development within the LY6G6D-targeted therapy landscape and its clinical evaluation in mismatch repair-proficient CRC.

EM1034 induced minimal target-independent cytokine release



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EM1034 demonstrated more potent *in vivo* anti-tumor efficacy against colorectal tumors with varied LY6G6D expression



We expect to submit an IND application for EM1034 for the treatment of solid tumors in the fourth quarter of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EM1034 SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

We believe that our continued research and development is the key driver of our business growth and competitiveness. Our R&D efforts are primarily driven by unmet clinical demand in complex diseases with a mission of treating the patients as a whole, by targeting multiple disease-critical pathways synergistically to improve overall clinical benefits in a well-balanced manner.

Our R&D Team

Our R&D team has strong expertise, deep understanding, and broad development experience in oncology and autoimmune diseases. Our R&D team is led by a team of experienced scientists with years of drug development experience. As of September 30, 2025, our core R&D personnel consisted of 47 members covering the fields of biology, antibody discovery, antibody engineering, pharmacology, and toxicology, among whom ten members hold a doctorate degree and 27 members hold a master’s degree. Our core R&D personnel possess an average of over 10 years of experience in the biopharmaceutical industry.

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Our R&D team is led by Dr. Wu, our founder and chief executive officer, Dr. Xuan Wu, Ph.D., Senior Director of Biology, Mr. Danqing Wu, Senior Director of Biologics Discovery, Mr. Shiyong Gong, Director of Biologics Engineering and Dr. Naren Gaowa, Ph.D., Director of Preclinical Toxicology:

- Dr. Chengbin Wu brings over 20 years of biopharma experience in biologics drug research and innovation, antibody engineering, and project leadership from concept to regulatory filing. Before founding our Company, Dr. Wu served as the chief scientific officer and president of R&D at 3Sbio, a leading China-based biopharmaceutical company. He also held the position of Senior VP Biologics at Shanghai ChemPartner, where he established comprehensive biologics R&D capabilities. Earlier in his career, Dr. Wu was a Volwiler Associate Fellow at AbbVie, United States. He is the primary inventor of the FIT-Ig technology, a bispecific antibody platform for developing next-generation biologics therapies. Dr. Wu received his Ph.D. from the University of Georgia and completed his postdoctoral training at Harvard Medical School in immunology with a research grant from the Cancer Research Institute, New York, NY. His extensive expertise and proven track record in antibody development and biologics R&D significantly bolster our technological capabilities and strategic objectives.
- Dr. Xuan Wu has extensive experience in drug discovery and development, with deep expertise in immunology and oncology. Prior to joining us, Dr. Wu served as a principle scientist and subsequently an associate director of the immuno-oncology platform at HD Biosciences Co., Ltd., a leading preclinical CRO wholly owned by WuXi AppTec Co., Ltd. (stock code: 02359.HK). Prior to that, Dr. Wu worked at Shanghai ChemPartner as a senior scientist in immunology department. Dr. Wu received his Ph.D. in Cellular Biology from the University of Edinburgh, with his research focused on inflammation and tissue fibrosis.
- Mr. Danqing Wu has established a strong track record of leading antibody discovery and advancing them into the clinic. Prior to joining us, he took multiple key R&D positions at renowned MNCs, including Novartis, GSK and Epitomics. Mr. Wu obtained his bachelor’s degree and master’s degree in biochemical engineering both from Zhejiang University.
- Mr. Shiyong Gong’s career demonstrates a consistent dedication to drug discovery and development. Prior to joining us, he honed his expertise in antibody discovery, screening and engineering at Chengdu Kanghong Pharmaceutical Group Co., Ltd. (stock code: 002773.SZ) and Shanghai ChemPartner. Mr. Gong received his bachelor’s degree in biotechnology and his master’s degree in biochemistry and molecular biology both from Huazhong Agricultural University.

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- Dr. Naren Gaowa brings broad experience in managing, operating and coordinating preclinical and IND-enabling studies with a deep understanding of GLP regulations. Prior to joining us, she has successfully led nonclinical studies at multiple leading companies across the pharmaceutical and life sciences industry, including Zai Lab Limited (stock code: 09688.HK), WuXi AppTec Co., Ltd. (stock code: 02359.HK) and Covance Pharmaceutical R&D (Shanghai) Co., Ltd. Dr. Naren Gaowa received her Ph.D. in Veterinary Pharmacology and Toxicology from China Agricultural University.

We maintain a highly systematic and collaborative R&D structure, with our R&D center comprising four specialized groups based on their respective roles in drug development: the antibody engineering group, the biologics discovery group, the preclinical toxicology group, and the biology group. Specifically, the biologics discovery group leads antibody screening efforts, the antibody engineering group focuses on bispecific optimization and generation, the biology group conducts in vitro and in vivo preclinical pharmacology studies, and the preclinical toxicology group oversees the preclinical evaluation of toxicity for lead candidates.

Together, these groups constitute an integrated R&D ecosystem that facilitates innovation, enhances efficiency, and upholds scientific rigor across the entire drug development pipeline. This structure enables seamless interdisciplinary collaboration, thereby expediting the translation of preclinical discoveries into clinically development.

Our Drug Discovery and Development Team

Our drug discovery and development team bring together relevant specialists from across our Company, as needed, throughout the development of a drug candidate. Our drug discovery function is led by Xuan Wu, Ph.D., Senior Director of Biology; Danqing Wu, Senior Director of Biologics Discovery; Shiyong Gong, Director of Biologics Engineering; and Naren Gaowa, Ph.D., Director of Preclinical Toxicology and consists of 47 employees as of September 30, 2025, among whom ten members hold a doctorate degree and 27 members hold a master’s degree.

Our R&D Capabilities

Drug discovery and antibodies engineering

For antibody discovery, we integrate and leverage a variety of advanced discovery platforms and technologies, primarily comprising phage display and hybridoma platforms, complemented by state-of-the-art mRNA immunization techniques and an automated screening system.

In biologics engineering, we have established an integrated platform including antibody humanization, affinity maturation, physicochemical property optimization, bispecific/multispecific construction, antibody-drug conjugation and developability assessment, which facilitates the candidate selection with various biological mechanisms.

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We have successfully identified and screened several monoclonal and bispecific antibodies from hybridomas, many of which have advanced to the clinical stage. This highlights the robust efficiency and effectiveness of our platform in identifying promising therapeutic candidates via rapid and systematic screening and selection processes.

For antibody engineering, we possess extensive capabilities in antibody humanization, novel biologics design, and protein engineering. By integrating computational modeling, high-throughput screening, and rational design, we effectively combine creativity with technical precision to develop safer, more potent, and manufacturable preclinical candidates.

In vivo and in vitro efficacy evaluation

Assessing the *in vivo* and *in vitro* activities of antibody drugs constitutes a pivotal step during the early discovery phase. Our biology team, possessing extensive expertise in the development of cell-based bioassays, has successfully established a broad spectrum of stable cell lines and refined numerous cell-based *in vitro* bioassays. Furthermore, we have designed primary immune-cell assays tailored to align with the mechanism of action for each specific target. Our capabilities also encompass the creation of diverse in-house animal models, which are employed for efficacy, pharmacodynamics, mechanism-of-action, and translational studies. Additionally, we perform preliminary toxicology assessments and pharmacokinetic analyses. These comprehensive evaluations ensure that our antibody candidates demonstrate robust efficacy and safety profiles, thereby establishing a robust foundation for advancement into clinical development.

Druggability assessment

We conduct comprehensive druggability assessments by integrating software-based analysis, physicochemical testing, immunoassays, accelerated stability studies, and PK evaluations. Through the systematic evaluation of candidate molecules across multiple parameters, we identify and prioritize lead molecules that fulfill stringent druggability requirements. This rigorous assessment process ensures that our lead candidates are optimally positioned for subsequent development stages and clinical success.

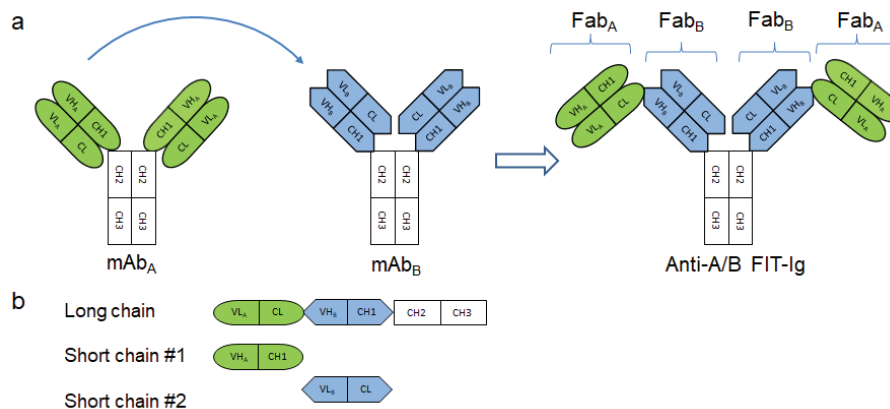
With our extensive R&D capabilities and a multidisciplinary strategy, we ensure that only the most promising and viable candidates progress through the development pipeline, thereby maximizing the potential for successful therapeutic outcomes.

Our Proprietary Technology Platforms

As of the Latest Practicable Date, we independently developed three proprietary technology platforms, including Fabs-In-Tandem Ig (“**FIT-Ig**”) Platform, Monovalent Asymmetric Tandem Fab (“**MAT-Fab**”) Platform and TCR-Fab In Tandem (“**T-FIT**”) Platform.

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FIT-Ig and MAT-Fab are specifically engineered to overcome chain mismatch complexity and format-selection challenges that have historically led to low development success of bispecific antibodies. By structurally fusing two parental Fab fragments into a single dual-targeting molecular entity and adopting a unique crisscross orientation of VH-CH1 and VL-CL, these formats inherently avoid heavy/light chain mispairing and the combinatorial assembly of unintended configurations. Both formats retain an Fc domain to form a disulfide-linked IgG-like molecule, enabling straightforward Protein A purification and efficient, consistent manufacturing.



Source: Company data

These formats also streamline the selection of an appropriate bispecific architecture. From parental mAbs, FIT-Ig and MAT-Fab leads can be rapidly generated in approximately 4-6 weeks to support fast preclinical iteration. Their tandem Fab geometry minimizes steric hindrance, allowing broad applicability to large cell-surface receptors and supporting multiple mechanisms of action, including immune cell engagement, dual receptor blockade, dual cytokine neutralization and bispecific ADCs, across oncology, autoimmune and inflammatory diseases. The IgG-based design demonstrates favorable manufacturing efficiency and feasibility for subcutaneous formulation to enhance patient compliance.

Platform translation to the clinic addresses the historically low success rate of bispecifics by enabling earlier identification of optimal candidates and reproducible manufacturing. The FIT-Ig-based EMB-06 (BCMA×CD3) demonstrated a differentiated safety profile in an ongoing first-in-human Phase I study in relapsed or refractory multiple myeloma, with only Grade 1-2 CRS, no ICANS, and durable efficacy, achieving an overall response rate of 39% across evaluable patients and 92% at doses ≥ 120 mg, alongside dose-proportional pharmacokinetics and a median half-life of 4.4 days. In parallel, the FIT-Ig format has demonstrated robust, scalable manufacturing suitable for commercial supply, and additional clinical evidence from other FIT-Ig molecules, including EMB-01 demonstrating encouraging efficacy signals in heavily pretreated metastatic colorectal cancer, supports generalizability of safety and efficacy across indications.

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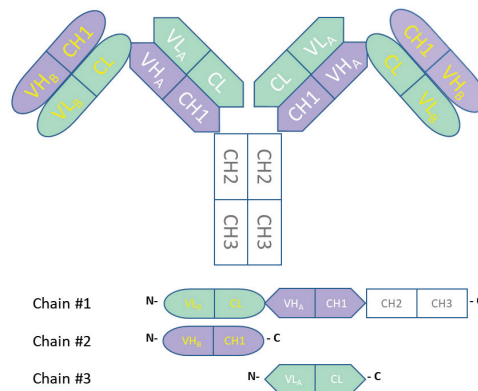
The chart below provides a concise summary of the key features and technological advancements of our three technology platforms as compared with industry benchmarks:

Developer		Company A	Company B	Company C	Company D	Company E	Our Company	Our Company	Our Company
Representative biologics		Drug A	Drug B	Drug C	Drug D	Drug E	EMB-01, EMB-06	EMB-07	undisclosed
Technology platform		A bsTCE Platform Bridging T Cells and Tumor Cells Using Bispecific Molecules	A Non-T-cell-engager Platform Addressing the Chain Mispairing Problem	A Non-T-cell-engager Platform based on Fab-arm Exchange	A bsTCE Platform Utilizing Long-acting T-cell Engagers	A bsTCE Platform based on TCR	FIT-Ig	MAT-Fab	T-FIT
Extra amino acid mutations for correct pairing of chains	Disadvantages: Need extensive molecular engineering and may increase immunogenicity potential	No*	Yes	Yes	Yes	Yes	No*	Yes	No*
Artificial peptide linkers between binding domains	Disadvantages: Need extensive molecular engineering and increase immunogenicity potential	Yes	Yes	No*	Yes	Yes	No*	No*	No*
Fab structure alteration to minimize light chain miss-pairing	Disadvantages: May reduce binding efficacy of parental Fab	Yes	Yes	No*	No*	No*	No*	No*	No*
Multiple process for stable cell line development and GMP production	Disadvantages: Increase CMC and GMP production cost	No*	No*	Yes	No*	No*	No*	No*	No*

: “No” is better

Source: Public information, Frost & Sullivan

Fabs-In-Tandem Ig (FIT-Ig) Platform



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Our FIT-Ig bispecific antibody technology platform introduces a structural design to address key challenges in bispecific therapeutics. By integrating two distinct Fab domains within a single IgG-based molecule without relying on artificial linkers or mutations, FIT-Ig preserves the natural antibody architecture while enabling dual-target engagement. This platform supports a “plug-and-play” approach, whereby a FIT-Ig bispecific molecule can be efficiently generated by incorporating any two parental antibody Fab sequences from existing monoclonal antibodies, without the need for extensive engineering or complicated procedures. This enables the rapid development of bispecific candidates from existing monoclonal antibodies in an average of four to six weeks. Currently, the platform has been well proven by the advancement of multiple candidates into clinical stage, including EMB-01 and EMB-06 and empowers our multiple preclinical-stage product candidates. Spanning diverse therapeutic mechanisms, such as tumor targeting, dual immune checkpoint modulation, and T-cell engagement, these candidates demonstrate the platform’s versatility across oncology indications.

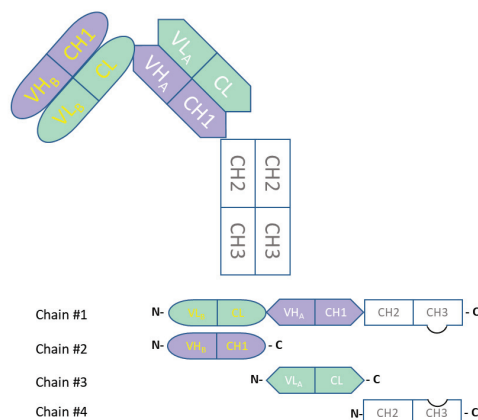
The FIT-Ig platform employs a unique 2+2 bispecific format, where two Fab regions targeting distinct antigens are incorporated into a single IgG-based molecule through precise molecular engineering. This design maintains the natural Fab structure and Fc region, ensuring both stability and effector function. FIT-Ig molecule contains three component chains: one carrying the long chain with VL_B-CL-VH_A-CH1-CH2-CH3 domains, and two short chains that are VH_B-CH1 and VL_A-CL, respectively. These component chains are co-expressed in mammalian systems such as CHO and HEK293 cells, resulting in a tetravalent bispecific antibody retaining antigen-binding affinities of the parental monoclonal antibodies. The workflow integrates high-throughput antibody screening, mRNA-based rapid immunization, and automated clone selection, enabling progression from target identification to preclinical candidate selection within 12 months. Downstream processes, including one-step Protein A purification, yield high-purity bispecific antibodies (>95% by SEC-HPLC) with scalable manufacturing processes comparable to conventional monoclonal antibodies.

The FIT-Ig platform overcomes the limitations of traditional bispecific antibody technologies, which often rely on complex engineering, artificial linkers, or mutations that result in instability, immunogenicity, or manufacturability issues. By retaining the native IgG structure, FIT-Ig platform ensures favorable pharmacokinetics, tissue penetration, and low immunogenicity. Low immunogenicity is further supported by Phase I clinical data of EMB-01: among 107 patients with evaluable baseline and postdose ADA results, 4 patients (3.7%) who were ADA negative at baseline developed treatment-emergent ADAs. In addition, 12 patients were ADA positive at baseline, of whom 5 had at least one postbaseline positive ADA result without any increase (≥ 1 fold) in ADA titer after treatment. Its unique design eliminates steric hindrance, enabling simultaneous engagement of targets like membrane-bound receptors and soluble antigens without functional interference. The platform’s rapid development cycle and compatibility with standard GMP-compliant processes reduce time-to-clinic and production costs, as evidenced by EMB-06’s high-yield manufacturing (~4 g/L titer) and potential subcutaneous administration. Clinically, FIT-Ig platform candidates have demonstrated robust efficacy, including EMB-06’s 92% ORR in relapsed multiple myeloma at the highest doses and

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EMB-01’s tumor penetration comparable to monoclonal antibodies. With broad patent coverage and validation across four clinical-stage assets, FIT-Ig platform represents a scalable, versatile solution for next-generation bispecific therapeutics, bridging the gap between design and commercial viability.

Monovalent Asymmetric Tandem Fab (MAT-Fab) Platform



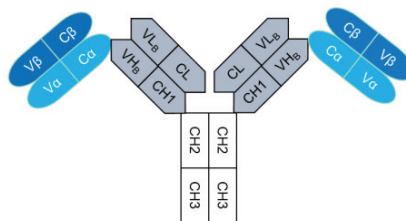
The MAT-Fab platform represents a bispecific antibody format designed to address longstanding challenges in therapeutic antibody engineering. Unlike traditional 1+1 bispecific formats such as BiTE, DART, or TandAb, which often rely on single-chain variable fragments with peptide linkers, the MAT-Fab platform employs tandemly linked Fab units in a crisscross fashion fused to an Fc region, combining monovalent binding for two distinct epitopes or antigens within a single asymmetric structure. This architecture comprises four polypeptide chains: a long chain (VL_B-CL-VH_A-CH1-hinge-CH2-CH3ml), an Fc chain (hinge-CH2-CH3m2), and two distinct short chains. The platform is particularly suited for T-cell redirecting applications, where it can simultaneously bind a tumor-associated antigen and an effector cell marker while modulating Fc-mediated effector function. Its modular design enables targeting diverse disease pathways, including oncology, autoimmune disorders, and infectious diseases, with potential advantages in stability and manufacturability.

The MAT-Fab platform leverages knobs-into-holes technology to drive heterodimerization between the long chain’s CH3ml domain and the Fc chain’s CH3m2 domain, ensuring proper assembly. Key structural innovations include direct fusion of adjacent domains (VL_B-CL-VH_A-CH1) without intervening linkers, eliminating immunogenic peptide spacers while maintaining binding affinity. The heavy chain integrates two Fab halves — VL_B-CL (specific for antigen “B”) and VH_A-CH1 (specific for antigen “A”) — followed by an Fc region with KiH mutations. Complementary short chains complete each Fab unit, enforcing correct pairing. Optional enhancements include disulfide bonds or salt bridges between CH3 domains to stabilize heterodimers. This design ensures monovalent binding to each target, reducing off-target cytokine storms — a critical advantage for TCEs. The platform supports further engineering, such as conjugation with payloads.

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The MAT-Fab platform uniquely addresses three major industry challenges: stability, specificity, and safety. Unlike single-chain bispecifics, which suffer from short half-lives and physical instability due to the absence of Fc regions, MAT-Fab antibodies incorporate an Fc domain to extend serum persistence. The asymmetric design mitigates light-chain mispairing — a pervasive issue in IgG-like bispecifics — through structural constraints that enforce correct heavy-light chain assembly. Clinically, the monovalent binding to each target reduces the risk of excessive T-cell activation and cytokine release syndrome, a dose-limiting toxicity observed with bivalent T-cell engagers. For example, while BLINCYTO developed by Amgen (blinatumomab) requires continuous infusion due to its rapid clearance, MAT-Fab’s Fc domain enables less frequent dosing. Moreover, the platform’s flexibility allows targeting of complex antigen pairs with high specificity. These advantages position MAT-Fab as a versatile solution for next-generation bispecific therapeutics across oncology, autoimmunity, and infectious diseases.

TCR-Fab In Tandem (T-FIT) Platform



T-FIT platform represents a breakthrough in bispecific therapeutic design, combining the precision of TCR targeting with the versatility of Fab-based engagers. By integrating TCR specificity with our proprietary CD3 antibody technology, the platform generates TCR-TCEs capable of recognizing intracellular tumor-specific targets, e.g., KRAS mutation, presented by peptide-HLA complexes on cancer cells. This unique approach enables the development of “off-the-shelf” immunotherapies with minimized off-target effects, and expands the targets scope to those that are usually not addressed by traditional antibodies.

The T-FIT platform leverages a modular bispecific architecture to preserve native TCR specificity while incorporating a CD3-engaging arm to redirect T cells toward tumor cells. Recombinant expression of T-FIT molecules shows proper pairing and functionality, yielding IgG-like, stable and manufacturable bispecific molecules. The platform’s workflow integrates advanced TCR discovery, high-throughput screening, and rapid recombinant expression in lab scale, enabling expeditious process from target identification to preclinical candidate selection. With one-step protein-A chromatography, lab-scale purification yields high-purity (>95%) T-FIT molecules with scalable titers comparable to conventional antibodies. By simultaneously engaging peptide-HLA complexes and CD3 on T cells, the platform triggers potent cytotoxic responses, as evidenced by preclinical models showing targeted tumor cell killing.

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The T-FIT platform overcomes key limitations of existing TCR-based therapies, which often face challenges such as being difficult to produce, having a short *in vivo* half-life and requiring extensive molecular engineering. Its bispecific design ensures robust T-cell activation without requiring leukapheresis, *ex vivo* TCR engineering or adoptive cell therapy. The platform’s “off-the-shelf” format reduces production complexity and costs compared to autologous cell therapies, with manufacturing processes adaptable to standard antibody production lines. Clinically, TCR-TCEs have demonstrated high specificity for tumor cells, and minimized off-target toxicity — a critical advantage over conventional T-cell engagers. The T-FIT platform offers a scalable solution that bridges the gap between TCR specificity and bispecific functionality.

Clinical Development

Our Clinical Development Team

As of September 30, 2025, our clinical development team consisted of 16 members, including two holding doctoral degrees and ten holding master’s degrees. The team is organized into key functional areas such as clinical science and strategy, clinical pharmacology, clinical operations, statistics and data management, biomarker and translational research, and quality assurance. Our clinical development function is led by Dr. Yonghong Zhu, who brings over 20 years of experience in clinical development, translational research, and discovery research across multinational corporations and biotech companies. Other key members include Ms. Qiaoyang Lu, head of statistics and data management, and Ms. Lin Cao, head of regulatory affairs. Collectively, the team offers diverse expertise spanning biotech and multinational corporations, global and China markets, as well as early- to late-stage development.

Our team has a proven track record of collaborating with health authorities to deliver high-quality clinical trials, driving pipeline advancements in both the Asia Pacific region and the United States. What distinguishes our clinical team is its balanced, strategic approach — seamlessly integrating rigorous execution, measured innovation, and robust data generation, all guided by a global outlook. Navigating complexity while maintaining operational excellence, our clinical development team ensures consistent progress across our development programs.

Our clinical development capabilities

Our clinical development capabilities are designed to comprehensively support the advancement of drug candidates from preclinical research to clinical applications. We specialize in formulating detailed target product profiles and crafting robust clinical development strategies and plans that align with regulatory requirements and scientific objectives. With expertise spanning all phases of clinical trials, our team oversees every aspect of the process, including trial design, execution, and the collection and analysis of data. Throughout this journey, we ensure the highest standards of data integrity, compliance with regulatory guidelines, and adherence to ethical principles.

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In addition to trial management, we excel in regulatory affairs, guiding drug candidates through the complex approval process with precision and efficiency. Furthermore, our capabilities include biomarker assay development and translational research, which are vital for bridging the gap between preclinical findings and their application in clinical settings. By integrating these elements, we ensure that our clinical programs are not only scientifically rigorous but also strategically positioned to deliver meaningful outcomes for patients.

Collaborations with CROs

In alignment with industry standards, we engage CROs to conduct and support our preclinical studies and clinical trials under our close supervision and overall management. We select CROs based on a variety of factors, including their qualifications, expertise, experience, reputation, and cost-effectiveness. Our partnerships with CROs are project-specific, ensuring tailored support for each initiative. The preclinical CROs typically provide services related to preclinical toxicity and safety evaluations, such as animal studies, as well as *in vivo* pharmacology and PK studies under our study design. The clinical CROs assist us with various aspects of our clinical trials, including trial preparation, clinical monitoring, medical monitoring, and project management. Leveraging the professional expertise of CROs, we are able to optimize site selection, facilitate timely patient recruitment and ensure the efficient conduct of complex clinical trials. We maintain rigorous oversight of CROs to ensure that their performance adheres to our protocols and applicable laws, safeguarding data integrity and the overall quality of our research.

Key terms of our agreements that we typically enter into with our CROs are set forth below:

- **Services.** The CROs provide services to us, including the implementation and management of a preclinical or clinical research project as specified in the agreement.
- **Term.** The CROs are required to perform their services and complete the preclinical or clinical research project within the prescribed time limit set out in each work order, usually on a project basis.
- **Payments.** We are required to make payments to the CROs in accordance with the payment schedule agreed by the parties.
- **Intellectual property rights.** We own all intellectual property rights arising from the preclinical or clinical research projects conducted by the CROs within the stipulated work scope.
- **Confidentiality.** Our CROs are not allowed to disclose confidential information, including but not limited to, any technical materials, research reports or trial data related to the project specified in the agreement, and such obligation generally survives for ten years.
- **Risk allocation.** Each party should indemnify the other party for losses caused by its fault or gross negligence.

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Chemistry, Manufacture and Controls

CMC Team

The CMC function in our Company is essential to the drug development process. It is responsible for developing safe, robust, and economically sound production processes for our drug substances and drug products, and ensuring their quality meets regulatory requirements. As of the Latest Practicable Date, our CMC team consisted of one professional with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. This individual is responsible for overseeing CDMO relationship and implementing quality control protocols. Given that we do not currently operate in-house manufacturing facilities and relies on established CDMOs with robust infrastructure and quality systems, the scope of internal CMC activities remains manageable. We believe that a single dedicated personnel is sufficient to ensure effective oversight and coordination at this stage of development. As the pipeline progresses toward late-stage clinical trials and commercialization, we plan to expand our CMC team in line with operational needs, regulatory complexity, and volume of production activities.

Collaborations with CDMOs

During the Track Record Period, we also outsourced certain manufacturing activities to industry-recognized CDMOs in China for preclinical and clinical supply of our drug candidates. We select CDMOs by carefully reviewing and considering various factors, such as their qualifications, expertise, production capacity, geographic proximity, reputation and pricing. We have adopted procedures to ensure that the production qualifications, facilities and processes of CDMOs comply with the relevant regulatory requirements.

Key terms of our agreements that we typically enter into with our CDMOs are set forth below:

- ***Services.*** The CDMOs provide us with manufacturing services according to cGMP requirements, quality standards and prescribed time frame as set out in the master agreement or work order.
- ***Quality control.*** The CDMOs are obliged to ensure that the quality of products meet the quality standards set out in the agreement and requirements of cGMP and other regulations, and to provide Certificate of Analysis.
- ***Payments.*** We are required to make payments to the CDMOs in accordance with the payment schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.
- ***Intellectual property rights.*** We own all product-related intellectual property rights arising from the outsourced manufacturing processes.

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- ***Confidentiality.*** Our CDMOs are not allowed to disclose confidential information, including but not limited to any technical materials, research reports or trial data related to the project specified in the agreement, and such obligation generally survives for ten years.
- ***Remedies for non-conforming products.*** If CDMOs fail to deliver products or comply with substantial obligations due to its own reasons under the relevant agreement, we are entitled to and request for late fees and compensation for losses due to the failure according to the work order.

Quality Control and Assurance

Quality control and quality assurance are paramount to our continued success. We operate a comprehensive outsourced quality management system that spans all key stages of our product lifecycle. This system is meticulously established in accordance with rigorous regulations and guidelines in China, the United States, and Europe. We closely monitor evolving cGMP standards and regulatory developments in these markets, continuously refining our partner oversight procedures to meet international standards for patient safety and regulatory compliance.

We conduct thorough qualification assessments of our CDMOs. This includes reviewing their GMP certificates, production licenses, and quality system certifications, as well as evaluating their technical capabilities and project team experience. Prior to collaboration, we perform on-site audits to inspect facilities, equipment, personnel training, deviation handling systems, and quality management documentation. Formal quality agreements are established to define responsibilities and standards.

During production, we implement active monitoring measures. Our team reviews manufacturing and quality control documents, including process procedures, batch records, and release testing standard operating procedures. We conduct on-site monitoring of the manufacturing process and rigorously review all deviations and changes. For critical raw material suppliers, we perform periodic on-site audits to ensure adherence to our quality requirements. In the product release phase, we enforce strict controls. This includes comprehensive review of release testing records, batch production documentation, and material release documents. We manage product stability programs and maintain proper handling of reference samples. Any required technology transfers are closely supervised to ensure seamless implementation.

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COMMERCIALIZATION AND BUSINESS DEVELOPMENT

We currently have no drug approved or in commercial stage yet. However, we have been building up our commercial planning and portfolio management capability since our pipeline drug candidates entered the late stages of clinical trials. We adhere to an asset-light model in devising our commercialization strategies, focusing on leveraging external expertise and resources rather than building and maintaining a large internal commercial infrastructure. This approach enables us to reduce upfront capital investment and operational overheads, thereby enhancing economic viability and allowing for more agile deployment of resources.

Sales and Marketing

In the short run, instead of expending extensive resources on establishing a dedicated sales and marketing team, we will primarily focus on working with contract sales organizations to utilize their distribution networks to accelerate product rollout and reduce time-to-market, leverage their sales and marketing capabilities, including their existing customer relationships, promotional infrastructure, and brand recognition, to drive product adoption without incurring the costs of building such capabilities in-house, and draw on market intelligence and insights provided by contract sales organizations to inform pricing strategies, target geographies, and positioning of products, ensuring commercial decisions are data-driven and aligned with market demand. As of the Latest Practicable Date, we had not entered into any definitive agreements, nor had we identified any specific potential contract sales organizations for such arrangements. We intend to pursue such arrangements as our pipeline drug candidates approach commercialization.

As of the Latest Practicable Date, we have not established an in-house sales and marketing team. However, in the long term, as we identify promising market opportunities, we intend to build a dedicated in-house sales and marketing team with deep expertise in our targeted therapeutic areas. This team will take on key responsibilities, including developing marketing strategies, defining product positioning, ensuring market access, driving market penetration, executing promotional activities, and providing patient support. We anticipate that this team will work in close collaboration with our partners to maximize the reach and impact of our products in major markets.

With respect to our Core Product EMB-01, we have developed an adaptive commercialization strategy aimed at accelerating market penetration in China following receipt of the relevant marketing approval. We plan to initially collaborate with leading contract sales organizations experienced in oncology, leveraging their extensive sales networks and distribution channels to facilitate rapid market entry and broaden coverage. At the same time, we intend to strengthen engagement with key opinion leaders and physicians to build advocacy for EMB-01, including identifying hospitals, clinics, and oncology specialists for pre-launch training and in-person outreach. In addition, we believe academic-driven marketing initiatives will be instrumental in aligning expert opinion and promoting clinical adoption. To this end, we have actively participated in, and will continue to attend and organize, academic conferences and seminars to share clinical data and research findings, thereby enhancing brand awareness and recognition.

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Pricing

We expect the pricing of our Core Product and key products to be determined by various factors such as (i) the competitive landscape of the addressable market at the time of our commercial launch, (ii) the value propositions of our Core Product and key products including drug efficacy and safety, (iii) the supply and production costs, and (iv) our pricing strategies. Our approach is designed to be flexible and adaptable to the distinct healthcare systems and payment structures of different markets where we plan to target. In China, we anticipate engaging in government-led negotiations to secure inclusion in the National Reimbursement Drug List to ensure affordability and patient access. In the United States and other jurisdictions, our strategy will be centered on value-based pricing, reflecting the clinical benefits of our products, and will involve negotiations with public and private payers. As the Core Product and key products are currently under clinical development and have not entered Phase III registrational stage as of the Latest Practicable Date, we have not formulated concrete pricing strategy at this stage, but we expect that the Core Product and key products will be priced at a fair premium compared to its competitors in China, reflecting its value propositions. For more details of pricing and reimbursement for comparable marketed innovative bispecific antibodies, see “Industry Overview — Bispecific Antibody: Bridging Precision Targeting and Immune Activation in Modern Therapy — Pricing and Reimbursement for Select Marketed Innovative Antibodies.” As our product candidates advance through clinical development, we will continue to refine our commercial strategy to align with market dynamics and regulatory requirements.

We intend to seek inclusion of EMB-01 in the NRDL, as well as in other alternative or complementary reimbursement programs and commercial insurance, through active engagement with relevant government authorities and key stakeholders. As one of the most clinically advanced candidates in its class, EMB-01 has the potential to be among the first wave of bispecific antibody therapies to reach the market for the treatment of mCRC patients in the third-line setting. Current third-line standards of care provide only limited benefit, underscoring the significant need for improved treatment options such as EMB-01, which has demonstrated encouraging early efficacy signals. Positioning third-line mCRC as the lead indication for EMB-01 enables us to pursue a clear regulatory pathway through a head-to-head superiority trial, with the potential to support future NRDL inclusion based on a robust data package. Following marketing approval, we plan to implement a phased commercialization strategy, targeting early market penetration within the first three to five years while simultaneously advancing reimbursement discussions with the NRDL and other healthcare agencies to broaden patient access as indications expand.

Manufacturing

As of the Latest Practicable Date, we did not have in-house manufacturing facility that was operational. We plan to continue engaging qualified CDMOs to manufacture our drug candidates in support of their further development and commercialization. We believe this strategy is both cost-effective and efficient, enabling us to concentrate our resources on discovery and clinical development activities.

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Potential Cannibalization Risk Management

We have designed our product pipeline to minimize the risk of market cannibalization among our drug candidates, ensuring that our portfolio remains complementary rather than competitive. EMB-01, which is being developed for the treatment of colorectal cancer, is strategically positioned in a distinct therapeutic area and market segment from our other pipeline assets that are directed toward hematologic malignancies, or autoimmune disorders, with distinct biological targets and treatment modalities. As such, EMB-01 does not overlap in indication, target patient population, or clinical application with any other product candidates currently under development by us.

To further mitigate any potential for internal competition, we employ a portfolio management framework that includes (i) indication mapping and market segmentation analysis during early-stage development to identify and avoid therapeutic overlap; (ii) strategic prioritization of assets based on unmet medical need, market opportunity, and differentiation from existing therapies; (iii) commercial planning and lifecycle management to ensure that each product is positioned with a unique value proposition and target market; and (iv) Ongoing review of pipeline alignment to maintain clarity in development focus and avoid dilution of commercial efforts.

Business Development

We have established cross-border business development capabilities across China and the United States. As of the Latest Practicable Date, our business development team comprises three dedicated professionals responsible for formulating and executing our business development initiatives. Led by our Chief Business Officer, Dr. Stephen Lensky, spearheads these efforts with more than 21 years of experience in the pharmaceutical sector, 15 of which have been dedicated to business development. Dr. Lensky served as the head of the Corporate Department for Strategic Transactions & Alliance Management at Boehringer Ingelheim GmbH, overseeing the negotiation and management of all strategic deals for the Prescription Medicines division. Earlier in his career, he led a team at Bayer responsible for commercial licensing across Europe and emerging markets. Holding a Ph.D. in organic chemistry, Dr. Lensky has been a member of the BioFIT Steering Committee since 2014. His proven expertise in executing business development strategies and assessing strategic partnerships enhances our efforts in this domain, strengthening our ability to achieve key business objectives. Our business development capabilities have been particularly validated by our strategic license and collaboration arrangements with Almirall, Candid and Juri. For details, see “— Material Collaboration and Licensing Arrangements.” As we bring our pipeline candidates into clinical stage and towards commercialization, we will continue to explore global and local collaboration and out-licensing opportunities with major players in the industry.

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MATERIAL COLLABORATION AND LICENSING ARRANGEMENTS

Option and Evaluation Agreement with Almirall

On August 3, 2023, we entered into an option and evaluation agreement (the “**Almirall Agreement**”) with Almirall, S.A. (BME: ALM) (“**Almirall**”) for the purpose of enabling Almirall to evaluate the potential of our proprietary FIT-Ig[®] platform. Almirall is a Spanish pharmaceutical company focused on medical dermatology, with headquarters in Barcelona, founded in 1944.

Under the Almirall Agreement, we granted Almirall a non-exclusive license (the “**Research License**”) to perform evaluations with the FIT-Ig Technology. The FIT-Ig Technology comprises our FIT-Ig patent rights, which cover the composition, use, or manufacture of a FIT-Ig, and our FIT-Ig know-how, which is the proprietary knowledge necessary to utilize these patent rights. The Research License is restricted to the performance of the evaluation during the term of the Almirall Agreement. Should Almirall intend to continue to develop a candidate identified during the evaluation, it has to take an Option as described below.

Under the Almirall Agreement, we granted Almirall three options, designated as Option A, Option B, and Option C (each, an “**Option**”), each of which allows Almirall to obtain exclusive, worldwide licenses to develop, manufacture, and commercialize FIT-Ig molecule directed to distinct antigen pair (a “**Selected FIT-Ig**”), together with all products comprising such Selected FIT-Ig directed to the same antigen pair (a “**Product Family**”) (collectively, a “**Licensed Product**”). The Licensed Product and the application of the underlying FIT-Ig Technology are not related to our Core Product (EMB-01) or key products (EMB-06, EMB-07). Under the Almirall Agreement, it is expressly excluded that Almirall may take an option that targets the same antigen pairs as any proprietary program pursued by us, including discovery, preclinical and clinical programs, thus including the Core and key products. Accordingly, the Licensed Product and our Core Product and key products are IP distinct, with no overlap or conflict.

The Research License allows Almirall to conduct certain preclinical evaluation activities during the entire term of the Almirall Agreement to identify potential FIT-Igs it desires for exercising an Option. Almirall assesses the candidates according to its own criteria and timelines for development of its products and elects to exercise its Options based upon them.

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Almirall’s exercise of an Option is subject to a gatekeeping procedure to confirm that the Selected FIT-Ig does not conflict with third-party rights or our own programs. Almirall submits a written request to a mutually agreed third-party gatekeeper for confirmation. Almirall must also reasonably ensure that the selected target pair under its request is not a target pair known or prone to be used for oncology indications. The gatekeeper, as a patent specialist, will not disclose the target pair to us, but we will keep the gatekeeper informed of any right or license granted to third parties and any of our proprietary programs so that the gatekeeper can perform its responsibilities. Once confirmation is received, Almirall may exercise the Option by delivering a partially executed license agreement (the “**Product Family License Agreement**”), which we will promptly execute with the effective date being the date of Almirall’s signature.

Each of the Option A, Option B and Option C is distinct and can be exercised independently. Almirall is the sole party with the right to exercise these Options. The Almirall Agreement is a single framework agreement that sets out the common background and principal terms applicable to all three Options, and the definitive Product Family License Agreements resulting from the exercise of any of the three Options are identical in form and serve as a standard template.

We retain all intellectual property rights to the FIT-Ig Technology and any improvements to FIT-Ig orientations, compositions or methods of making or using a FIT-Ig developed by Almirall in its practice of license thereunder, except those specific to the Product Family, and Almirall shall assign to us all right, title, interest in and to all FIT-Ig Improvements that are not Product Family specific.

Disputes that cannot be resolved by senior executives within a specified time may be submitted to binding arbitration under the ICC Rules. The Almirall Agreement will expire 30 months after its effective date unless earlier terminated. Either party may terminate the Almirall Agreement on account of the other party’s uncured material breach or insolvency upon written notice, and Almirall may terminate the Almirall Agreement at any time for convenience upon written notice.

Upon exercise of an Option, the parties enter into a definitive Product Family License Agreement, under which Almirall is granted an exclusive, worldwide license under our FIT-Ig Technology to research, develop, manufacture and commercialize the Licensed Product. Almirall is responsible, at its own cost, for all research, development and commercialization activities relating to the Licensed Product.

In return, we are eligible to receive non-refundable and non-creditable upfront payment. In addition, we are entitled to milestone payments upon the achievement of specified development and regulatory events with the first FIT-Ig, including first dosing in a good laboratory practice toxicology study, IND/CTA filing, first dosing in a Phase II clinical study, first dosing in the first pivotal clinical trial, and product launch in the United States, China, and certain countries in major European market, as well as sales milestone payments contingent upon the launch and commercial success of the relevant products. The total potential development, regulatory and sales milestone payments amount up to US\$210 million, subject

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to Almirall’s exercise of all three Options. Further, we are entitled to low single-digit royalties on net sales for any commercialized product. Such royalties are payable on a country-by-country basis. Our entitlement to payments under the Almirall Agreement arises from Almirall’s exercise of Options and subsequent development and commercialization of the Licensed Products. Such payments are independent of, and not contingent upon, any relationship to our existing drug candidates, which remain outside the scope of the Almirall Agreement. Each Product Family License Agreement will remain in effect until the fulfilment of the last payment obligation of Almirall to us, unless earlier terminated by the parties. The dispute resolution and termination mechanisms of the Product Family License Agreement are substantially the same as those in the Almirall Agreement.

In May 2025, Almirall exercised an Option and we entered into a Product Family License Agreement with Almirall for a Selected FIT-Ig and corresponding Product Family. As of the Latest Practicable Date, we have received an aggregate of US\$1 million from Almirall, comprising the upfront payment and a milestone payment triggered by the first dosing of the Licensed Product in a good laboratory practice toxicology study.

License and Collaboration Agreement with Candid for EMB-06

On August 5, 2024, we entered into a license and collaboration agreement (the “**EMB-06 License and Collaboration Agreement**”) with Vignette Bio, Inc., a clinical-stage company formed in 2024 and incubated by Foresite Labs, with a focus on innovative therapies to address immunology and inflammation associated diseases. Foresite Labs is a biotech incubator based in San Francisco, CA, United States. In September 2024, Vignette Bio, Inc. was acquired by Candid, a clinical-stage biotechnology company focused on researching and developing T-cell engager antibodies for therapeutic uses, including for treatment of autoimmune diseases. Candid was established in 2024 and is headquartered in San Diego, CA, United States. Through this acquisition, Candid possesses all the rights, powers, restrictions and duties of Vignette Bio, Inc. under the EMB-06 License and Collaboration Agreement. While Vignette Bio, Inc. and Candid were only recently founded in 2024, the core team members possess an exceptional track record in successfully building multibillion-dollar companies, including RayzeBio, Inc. (NASDAQ: RYZB), which was acquired by Bristol Myers Squibb (NYSE: BMY) for over US\$4 billion in 2024. Furthermore, collaborating with Vignette Bio, Inc. and Candid provided us with a strategic opportunity to expand our capabilities in immunology and gain a presence in the U.S. market. The strategic alignment of goals, combined with the proven expertise of the leadership team, provided a strong foundation for these collaborations, despite the companies’ recent establishment.

Pursuant to the EMB-06 License and Collaboration Agreement, we granted Candid an exclusive, royalty-bearing and sublicensable license under our Licensed Technology (as defined below) to research, develop, manufacture and commercialize EMB-06 and BCMA/CD3 bispecific antibodies that resemble minor structural modifications of EMB-06 but remain within the scope of EMB-06 patents, for the diagnosis, treatment or prevention of all human and non-human diseases (the “**Field**”) outside China (including Hong Kong, Macau and Taiwan) (the “**Candid Territory**”). As of the Latest Practicable Date, EMB-06 is the only drug

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candidate licensed to Candid under the EMB-06 License and Collaboration Agreement, and no other derivatives of EMB-06 have been developed or are subject to the collaboration. The Licensed Technology comprises licensed patents and licensed know-how that are controlled solely by us and specifically cover any BCMA/CD3 bispecific antibody as a whole molecule or use of such molecule, or any CDR sequence contained in any domain directed to BCMA, and all Product-Specific claims within any other Licensed Patents. The exclusivity of this license is with respect to all product-specific (the “**Product-Specific**”) Licensed Patents. Additionally, we granted Candid a royalty-free, non-exclusive, sublicensable license under the Licensed Technology to (i) research and develop EMB-06 in the Field in China (including Hong Kong, Macau and Taiwan) (the “**EpimAb Territory**”) for the purposes of obtaining regulatory approvals of EMB-06 in the Candid Territory, or (ii) manufacture EMB-06 in the EpimAb Territory solely for the research, development or commercialization of EMB-06 in the Field in the Candid Territory, or carry out the activities in foregoing (i). We retain all of the R&D and commercialization rights with respect to EMB-06 in the EpimAb Territory.

The EMB-06 License and Collaboration Agreement provides that, upon Candid’s initiation of a pivotal clinical trial of EMB-06 intended to enable the preparation and filing of marketing authorization application in the Candid Territory, we may initiate studies for our own regulatory submissions in the EpimAb Territory and are responsible for them at our own expense. Candid is responsible for the development of EMB-06 in the Candid Territory at its own expense. Nonetheless, in order to accelerate early clinical development of EMB-06 worldwide, Candid may, although it does not have any commercialization rights in China, conduct clinical trials in the EpimAb Territory for the purposes of obtaining regulatory approval in the Candid Territory. Therefore, to expedite worldwide development of EMB-06 and in compliance with the EMB-06 License and Collaboration Agreement, Candid is conducting clinical trials of EMB-06 for systemic lupus erythematosus and generalized myasthenia gravis in China, as well as investigator-initiated study. This arrangement allows us to leverage global development efforts while ensuring that our development and regulatory activities in China remain under our control and consistent with our contractual rights. For clarification, we will be the named marketing authorization holder of the regulatory approvals of EMB-06 in the EpimAb Territory. Accordingly, the respective roles of our Group and Candid for development activities in China are clearly delineated: Candid’s activities in China are limited to clinical trials for the purposes of obtaining regulatory approval in the Candid Territory, while we retain exclusive rights and responsibilities for development and commercialization in the EpimAb Territory. All such activities are in compliance with the EMB-06 License and Collaboration Agreement.

Under the EMB-06 License and Collaboration Agreement, we agreed to wind down our ongoing multi-center Phase I/II clinical trial of EMB-06 for oncology indications according to a wind-down plan defined in the EMB-06 License and Collaboration Agreement. The wind-down plan involves wrapping up the Phase I dose-escalation portion of the Phase I/II clinical trial of EMB-06 for relapsed or refractory multiple myeloma, not pursuing Phase II dose-expansion portion, and notifying trial sites in China and Australia of the study closure. The rationale for this wind-down is to avoid any potential impact of the ongoing oncology trial in China on Candid’s conduct of clinical trials of EMB-06 in autoimmune indications and its

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future regulatory submissions in the Candid Territory. The wind-down plan allows each party to pursue its respective development strategy without creating duplicative or conflicting clinical activities. Following the wind-down, we will not develop or license EMB-06 in the EpimAb Territory until Candid initiates a pivotal clinical trial of EMB-06. Upon Candid’s initiation of a pivotal clinical trial of EMB-06, we intend to join such pivotal clinical trial and develop EMB-06 in autoantibody-related autoimmune diseases/indications in China.

The clinical data we generated in oncology indications in China were transferred to Candid according to our obligations under the EMB-06 License and Collaboration Agreement and in compliance with applicable laws. In return we will have access to all data generated by Candid. We may use such obtained data to support our own regulatory submissions in the EpimAb Territory.

We and Candid have established a joint steering committee to review each party’s activities with regard to the development, manufacture and commercialization of EMB-06. We will have the final decision-making authority over the development, manufacture and commercialization of EMB-06 in the EpimAb Territory, provided, however, that Candid will have final decision-making authority over the manufacturing of EMB-06 prior to the first regulatory approval by Candid in the United States or as to any matter that could reasonably be expected to negatively impact the manufacture, development or commercialization of EMB-06 in the Candid Territory.

Pursuant to the EMB-06 License and Collaboration Agreement, in August 2024, we received a non-refundable and non-creditable upfront payment of low-to-mid-double-digit million U.S. dollars from Vignette Bio, Inc. Additionally, we are eligible to receive a total of US\$575 million non-refundable and non-creditable milestone payments upon the achievement of specified development, regulatory and sales milestones, including initiation of certain clinical trials, and regulatory approval in specified jurisdictions, and achievement of certain annual net sales thresholds, among other events. The total potential development and regulatory milestone payments amount to high-double-digit million U.S. dollars. To date, no milestone payments have become due under the EMB-06 License and Collaboration Agreement. Candid is also required to pay us tiered single-digit royalties on net sales of EMB-06 in the Candid Territory. Such royalties are payable on a country-by-country basis until the latest of (i) the expiration of the last valid claim within the licensed patents covering EMB-06 in the applicable country; (ii) the expiration of regulatory exclusivity for EMB-06 in such country; and (iii) the twelfth anniversary following the first commercial sale (the “**Royalty Term**”) in such country. As partial consideration for the licenses and rights granted by us to Candid, Candid issued certain of its Series A preferred shares to us. For further details, see Note 27(a)(2) to the Accountants’ Report set out in Appendix I to this document. As of the Latest Practicable Date, we had received an upfront payment of US\$30.0 million from Candid pursuant to the EMB-06 License and Collaboration Agreement.

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Under the EMB-06 License and Collaboration Agreement, each party shall solely own rights to all inventions invented or otherwise first created solely by or on behalf of such party. The parties will jointly own rights to all inventions invented or otherwise first created jointly by or on behalf of Candid and us. Candid has the first right to prosecute product-specific patents in the Candid Territory, while we have the sole right to prosecute product non-specific patents worldwide.

The EMB-06 License and Collaboration Agreement will remain in effect until the expiration of the Royalty Term, unless earlier terminated by the parties. Each party may terminate the EMB-06 License and Collaboration Agreement on account of the other party’s uncured material breach or insolvency upon written notice. Candid may unilaterally terminate the EMB-06 License and Collaboration Agreement at any time for convenience in its entirety with prior written notice to us. We may also terminate the EMB-06 License and Collaboration Agreement in the event that Candid, individually or in association with any other person, commences a legal or administrative action challenging the patentability, validity, enforceability or scope of patent rights licensed to Candid owned or controlled by us anywhere in the world. The EMB-06 License and Collaboration Agreement contains standard dispute resolution proceedings among the parties escalating, if necessary, up to the chief executive officers, which shall, in the event of failure to resolve any disputes, submit to arbitration administered by JAMS under the JAMS International Arbitration Rules then in effect. Notwithstanding the above, disputes with respect to intellectual property rights cannot be submitted to an arbitration proceeding, unless otherwise agreed by the parties in writing, and instead either party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

License and Collaboration Agreement with Candid to Discover and Develop Multi-specific Antibody Assets

On November 29, 2024 (the “**Effective Date**”), we entered into a license and collaboration agreement (the “**Candid Agreement**”) with Candid. Pursuant to the Candid Agreement, during the Research Term (as defined below), we will conduct the research programs (the “**Research Programs**”) for the generation, design, discovery and characterization of multi-specific antibodies (each, a “**Research Compound**”) in accordance with a comprehensive written plan (the “**Research Plan**”). The Research Plan delineates (i) a description of the research activities to be performed by us, (ii) a timeline for performance of the research activities, (iii) the minimum number of FTEs that we shall dedicate to the performance of the research activities, (iv) the budget for out-of-pocket costs for the research activities, and (v) any Candid background technology to be used by us. The Research Plan serves as the operational blueprint that translates the broader strategic objectives of the Candid Agreement into concrete, measurable, and enforceable actions. The Research Plan is a binding instrument for both parties under the Candid Agreement. “**Research Term**” means, on a Research Program-by-Research Program basis, an initial period commencing on the Effective Date and expiring upon the earlier of (i) three years after the Effective Date, or (ii) completion of the research activities set forth in the Research Plan, provided that, the Research Term shall automatically extend for successive 12 month periods unless either party provides at least ninety 90 days’ notice prior to the end of the then current Research Term that it does not wish to renew, and in each case unless earlier ended in accordance with the Candid Agreement.

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With respect to each Research Program, we are responsible for antibody engineering and optimization, performance of *in vitro* assays and cell-based studies and performing vivo testing, while Candid has sole decision-making authority and the sole right to manage the performance of the Research Programs under the Research Plan, to identify targets, guide molecular engineering, experiments, and development and validation of biomarkers. On a Research Program-by-Research Program basis, Candid shall have the right to select one or more Research Compounds generated, designed, discovered, developed or characterized under the Research Programs (the “**Program Compounds**”) or controlled by us as of the Effective Date (the “**EpimAb Compounds**”) that Candid wishes to advance to full IND-enabling studies (such Program Compound or EpimAb Compound thereafter, a “**Selected Development Candidate**”). The Program Compounds and the EpimAb Compounds refer to either a tri-specific antibody targeting specified targets, or a bispecific antibody targeting specified targets. Under the Candid Agreement, it is expressly excluded that Candid may select a Selected Development Candidate that targets the same antigen pairs as any proprietary program pursued by us, including discovery, preclinical and clinical programs, thus including the Core and key products. Accordingly, these compounds are distinct from our Core Product (EMB-01) and key products (EMB-06, EMB-07) and will not be related to or compete with them. As of the Latest Practicable Date, no Selected Development Candidate had been identified or selected by Candid under the Candid Agreement. The provision in the Candid Agreement that allows Candid to select one or more antibody assets to advance into IND-enabling studies reflects a standard strategy commonly used in early development of products. It mitigates the risk that one selected candidate may fail to advance in development, enabling the licensee to revert to one or more back-up candidates.

Pursuant to the Candid Agreement, we granted Candid a royalty-bearing and sublicensable license under our applicable controlled patents and know-how (the “**Licensed Technology**”) to research, develop, manufacture and commercialize the EpimAb Compounds, the Program Compounds, and their derivatives or modifications (the “**Derivative Compounds**,” together with the EpimAb Compounds and the Program Compounds, the “**Compounds**”), as well as the products (the “**Products**”) containing the Compounds as active ingredients in all human and non-human use, including for all research, diagnostic and therapeutic purposes (the “**Field**”) worldwide. The license granted to Candid is (i) exclusive with respect to all Product-specific licensed patents (the “**Licensed Patents**”) that are controlled by us and cover any Compound or Product or the use thereof in the Field, all Product-specific claims within any other Licensed Patents, and all know-how related thereto, and (ii) non-exclusive with respect to all claims within the non-Product-specific Licensed Patents, and all know-how related thereto. Candid granted us a non-exclusive, non-sublicensable license (except to subcontractors approved for our research activities) under certain of its patents and know-how solely for us to perform our activities under the Research Programs and IND-enabling activities as requested by Candid. Under the Candid Agreement, Candid shall, in its discretion and at its own expense, have the sole right to the regulatory matters of, and the sole responsibility for the development, manufacturing, commercialization and other exploitation of, the Compounds and the Products (as applicable) in the Field worldwide.

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Pursuant to the Candid Agreement, in December 2024, we received a non-refundable and non-creditable upfront payment of mid-single-digit million U.S. dollars from Candid. Further, Candid will reimburse us for costs incurred by us in the conduct of research activities in accordance with the Research Plan and budget. Additionally, for each Selected Development Candidate (even if multiple Selected Development Candidates are selected per each Research Program), we are eligible to receive non-refundable and non-creditable milestone payments upon the achievement of specified development and regulatory milestones events by any Product containing such candidate, including initiation of certain clinical trials, and regulatory approval in specified jurisdictions, among other events. The total potential development and regulatory milestone payments for each Selected Development Candidate amount to low triple-digit million U.S. dollars. We are also eligible to receive non-refundable and non-creditable sales milestone payments of up to mid-triple-digit million U.S. dollars per Selected Development Candidate. To date, no milestone payments have become due under the Candid Agreement. Candid is also required to pay us tiered royalties, on a Selected Development Candidate-by-Selected Development Candidate basis, worldwide, ranging from low to mid-single-digit percentages, subject to certain customary reductions and royalty floor. Such royalties are payable on a Product-by-Product and country-by-country basis, until the latest of (i) the expiration of the last valid claim; (ii) the expiration of all regulatory exclusivity for such Product in such country; and (iii) the twelfth anniversary of the first commercial sale of a Product in such Country (the “**Royalty Term**”). As of the Latest Practicable Date, we have received an aggregate of approximately US\$6.0 million from Candid under the Candid Agreement, comprising the upfront payment and research service fee.

Under the Candid Agreement, Candid shall solely own all Compounds and Product-specific research inventions invented in performance of the Research Program or IND-enabling activities, including (i) the entire sequences and formulations of the Selected Development Candidates and Research Compounds and (ii) certain Product-specific CDRs newly generated by us during the Research Program. We shall solely own rights to all non-Product-specific research inventions that specifically relate to (i) the FIT-Ig technology, (ii) the MAT-Fab technology, or (iii) any new formats discovered and/or developed by us during the Research Term. We and Candid shall jointly own rights to all inventions, not covered by the above separation of ownership, specifically modifications of generic antibody sequences as well as non-selected Product-specific CDRs.

The Candid Agreement contains standard dispute resolution proceedings among the parties escalating, if necessary, up to the chief executive officers, which shall, in the event of failure to resolve any disputes, submit to arbitration administered by JAMS under the JAMS International Arbitration Rules then in effect. Notwithstanding the above, disputes with respect to intellectual property rights cannot be submitted to an arbitration proceeding, unless otherwise agreed by the parties in writing, and instead either party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

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Upon expiration (but not earlier termination) of the Royalty Term with respect to a particular Product in a particular country, the license granted by us to Candid with respect to such Product in such country shall become non-exclusive, fully paid-up, freely sublicensable (through multiple tiers), royalty-free, perpetual and irrevocable. Each party has the right to terminate the Candid Agreement on account of the other party’s uncured material breach or insolvency upon written notice. Candid has the right to unilaterally terminate the Candid Agreement at any time for convenience, in its entirety or on a Research Program-by-Research Program basis, with prior written notice to us. We have the right to terminate the Candid Agreement in the event that Candid, individually or in association with any other person, commences a legal or administrative action challenging the patentability, validity, enforceability or scope of patent rights licensed to Candid.

License Agreement with Juri on KLK2/CD3 TCE Assets

On May 21, 2025, we entered into a license agreement (the “**Juri Agreement**”) with Juri Biosciences, Inc. (“**Juri**”), a biotech portfolio company incubated by TCG Labs Soleil headquartered in San Francisco, CA, United States, with a focus on efficiently translating scientific insights into therapeutic solutions for patients facing serious diseases. Pursuant to the Juri Agreement, we granted Juri an exclusive, royalty-bearing, and sublicensable license for Juri to research, develop, manufacture and commercialize licensed compounds and licensed products that target KLK2 for all uses, including the treatment of metastatic prostate cancer (the “**Field**”) globally (the “**Territory**”). Juri received an exclusive license to our patents and know-how covering any compounds targeting KLK2, including our development-ready TCE targeting KLK2 and CD3. In addition, we granted Juri an exclusive and sublicensable license under our TCE platform patents (“**TCE Platform Patents**”) covering certain KLK2 compounds that Juri selects to develop, manufacture and commercialize. As of the effective date of the Juri Agreement, EM1031, a preclinical-stage KLK2/CD3 TCE is the only drug candidate that we had developed and that was part of the KLK2/CD3 program licensed to Juri under the Juri Agreement. Since then, the program is being advanced to development solely by Juri.

We made the strategic decision to grant exclusive worldwide rights for EM1031 and related KLK2/CD3 assets to Juri to maximize the asset’s global potential through a single, highly specialized partner. A global, rather than regional, license structure was chosen to ensure unified development of the KLK2/CD3 assets by Juri while providing us with non-dilutive capital through upfront payment, potential milestone payments and tiered royalties. The out-licensing of EM1031 and related KLK2/CD3 assets will not affect the clinical development or commercialization of any other drug candidates in our pipeline. The exclusivity granted to Juri is compound-specific and limited only to the development and commercialization of KLK2-targeting compounds. We retain rights to our proprietary multi-specific antibody platforms for the global development of all other non-KLK2 targeting candidates.

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As consideration for the license, we are eligible to receive up to US\$210 million, including an upfront payment and milestone payments tied to development, regulatory, and commercial events, plus tiered royalties of low-single-digit percentage on net sales of licensed products in the Territory, payable on a country-by-country basis until the later of expiration of the relevant patent rights or the tenth anniversary following first commercial sale. As of the Latest Practicable Date, we have received an upfront payment of US\$10.0 million from Juri pursuant to the Juri Agreement.

Under the terms of the Juri Agreement, Juri assumes all development and commercialization responsibilities for the licensed compounds and licensed products. Each party shall solely own rights to all inventions invented or otherwise first created solely by or on behalf of such party. The parties will jointly own rights to all inventions invented or otherwise first created jointly by or on behalf of Juri and us. Juri has the first right to prosecute patents licensed to Juri other than the TCE Platform Patents in the Territory, while we have the sole right to prosecute TCE Platform Patents worldwide.

The Juri Agreement remains in effect until one year following the expiration of the last to expire royalty term, unless earlier terminated by the parties. Each party may terminate the Juri Agreement on account of the other party’s uncured material breach, insolvency or other specified events upon written notice. Juri may unilaterally terminate the Juri Agreement at any time for convenience in its entirety with prior written notice to us. The Juri Agreement contains standard dispute resolution proceedings among the parties escalating, if necessary, up to the senior executives, which shall in the event of failure to resolve any disputes, submit to arbitration administered by ICC under its Rules of Arbitration then in effect. However, disputes with respect to intellectual property rights cannot be submitted to an arbitration proceeding, unless otherwise agreed by the parties in writing, and instead either party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. 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) six issued patents in China, (ii) four issued patents in the United States, (iii) 47 issued patents in other jurisdictions, and (iv) 76 pending patent applications, including seven in China, nine in the United States, and 60 in other jurisdictions. For more details, see “Statutory and General Information — B. Further Information about the Business of our Company — 2. Our Material Intellectual Property Rights” in Appendix V to this document.

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As of the Latest Practicable Date, with respect to our Core Product, EMB-01, we owned two issued patents in China, three issued patents in the United States, and 28 issued patents in other jurisdictions (covering all relevant patent families, including FIT-Ig/EMB-01/EMB-06), along with six patent applications, including two in the United States and four in other jurisdictions.

The following table sets forth the portfolio of patents and patent applications material to our business operations as of the Latest Practicable Date (for each drug candidate and technology platform, all the counterparts in its related patent family are set forth in the following table):

Technology Platform/Drug Candidate	Patent/Patent Application	Patent Holder/Applicant	Jurisdiction	Status	Patent Expiration*
FIT-Ig/EMB-01/ EMB-06	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	Australia, Canada, Hong Kong, Macau, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Taiwan, United States, and South Africa	Granted	2034
	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	the PRC	Granted	2035
	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	Europe, United States	Pending	N/A
EMB-01	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	Australia, Brazil, Canada, the PRC, Macau, Cuba, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, and Taiwan	Granted	2037
	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	United States	Granted	2039
	Fabs-in-tandem immunoglobulin and uses thereof	Our Company	Europe, Hong Kong, United States, and South Africa	Pending	N/A

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Technology Platform/Drug Candidate	Patent/Patent Application	Patent Holder/Applicant	Jurisdiction	Status	Patent Expiration*
EMB-06	Antibodies to CD3 and BCMA, and bispecific binding proteins made therefrom	EpimAb Shanghai	Taiwan, Japan	Granted	2040
	Antibodies to CD3 and BCMA, and bispecific binding proteins made therefrom	EpimAb Shanghai	Australia, Brazil, Canada, the PRC, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, United States, and South Africa	Pending	N/A
MAT-Fab/ EMB-07	Monovalent asymmetric tandem Fab bispecific antibodies	Our Company	Australia, Hong Kong, Europe, India, Japan, Russia, and Taiwan	Granted	2037
	Monovalent asymmetric tandem Fab bispecific antibodies	Our Company	the PRC	Granted	2038
	Monovalent asymmetric tandem Fab bispecific antibodies	Our Company	Canada, New Zealand, and United States	Pending	N/A
EMB-07	Anti-ROR1 antibodies	EpimAb Suzhou; Epimab Shanghai	the PRC	Granted	2041
	Anti-ROR1 antibodies	EpimAb Suzhou; EpimAb Shanghai	the PRC, and Hong Kong	Pending	N/A
	Anti-ROR1 antibodies and related bispecific binding proteins	EpimAb HK	Japan, Russia	Granted	2041
	Anti-ROR1 antibodies and related bispecific binding proteins	EpimAb HK	Australia, Brazil, Canada, Hong Kong, Europe, Israel, India, South Korea, Mexico, New Zealand, Taiwan, United States, and South Africa	Pending	N/A

* Patent expiration date does not include any applicable patent term extensions except for mainland China and the United States.

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The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends on many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction, and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any such patents that may be issued in the future 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.

As of the Latest Practicable Date, we had (i) one registered trademark in China, (ii) nine trademark applications in China, and (iii) five registered trademarks in other jurisdictions. We are also the registered owner of 17 domain names.

We enter into license and collaboration agreements and other relationships with biopharmaceutical companies and other industry participants, through which we may grant access to our own intellectual property. See “— Material Collaboration and Licensing Arrangements.”

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.

A freedom-to-operate search and analysis (“**FTO Analysis**”) has been conducted in China 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 China covering the constructs, amino acid sequences, chemical structures or indications currently under development of our Core Product.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. 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.

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We have implemented a series of security measures, including data encryption, access control, anti-virus and anti-malware solutions, firewalls, intrusion detection systems and data backup and recovery protocols, to strengthen data security and privacy protection. We have established procedures to protect the confidentiality of patients’ data. We maintain policies requiring our personnel to be trained to collect and safeguard personal information and our agreements with the CROs contain data protection provisions providing that the CROs are responsible for safeguarding data in their possession. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel.

Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form (the “ICF”). We will obtain consent from patients if any use of data falls outside the scope of ICF.

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, the United States, as well as other applicable countries or regions. Together with our CROs and other collaboration partners, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the transfer of all clinical trial data or other potentially sensitive information. Related measures include, as applicable, ensuring that the cross-border transfer of this clinical data and information is permitted, any requisite approvals are properly obtained, and applicable filings are made, in each case, with the competent authorities and in accordance with relevant laws and regulations (particularly in the case of any transfer between China, the United States, as well as other applicable countries or regions). Our Directors confirm that we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable PRC laws and regulations for data privacy and protection as of the Latest Practicable Date.

As advised by our PRC data compliance advisor, Commerce & Finance Law Offices, we have complied with the applicable laws and regulations of the PRC concerning data security and personal information protection in material respects. In terms of cross-border data transfer, we have completed the filing of the Standard Contract for the Outbound Transfer of Personal Information in accordance with the relevant requirements for the provision of data abroad under PRC law and Measures on the Standard Contract for the Cross-Border Transfer of Personal Information. We have complied with the applicable laws and regulations of the PRC concerning cross-border data transfer in all material respects. In terms of cybersecurity review, in accordance with Article 7 of the Cybersecurity Review Measures, an online platform operator that possesses personal information of more than one million users shall declare to the Office of Cybersecurity Review before going public abroad. Our proposed [REDACTED] does not constitute “going public abroad” and thus does not require a proactive filing for cybersecurity review in respect of the [REDACTED] in accordance with Article 7 of the Cybersecurity Review Measures. See “Regulatory Overview — PRC Laws and Regulations — Regulations on Information Security and Data Protection” for details of relevant cybersecurity, data protection and user privacy laws and regulations.

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RAW MATERIALS AND SUPPLIERS

Suppliers

During the Track Record Period, our suppliers primarily consisted of CROs and CDMOs. Purchases from our five largest suppliers in aggregate in each year/period were RMB88.9 million, RMB39.8 million and RMB33.8 million, respectively, representing 62.3%, 43.5% and 32.8% of our total purchases for the respective periods. Purchases from our single largest supplier in each year/period were RMB39.3 million, RMB14.1 million and RMB14.8 million in each period during the Track Record Period, representing 27.5%, 15.4% and 14.4% of our total purchases for the respective periods. We believe that we maintain strong and stable relationships with our major suppliers.

We select our suppliers based on their quality, costs, delivery standards, and compliance with or qualification under relevant regulations and industry standards. We believe that we maintain stable 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.

The following table sets forth details of our five largest suppliers during the Track Record Period:

Supplier	Supplier background	Service purchased	Year(s) of business relationship	Credit term granted	Purchase amount	% of total purchases
<i>(RMB'000)</i>						
<i>For the nine months ended September 30, 2025</i>						
Tarlead Biotechnology (Suzhou) Co., Ltd. (泰禮生物技術(蘇州)有限公司)	A leading CDMO established in 2022 and headquartered in Shanghai	CDMO Service	Since 2023	Within 15 business days	14,755	14.4
Supplier E	A leading CDMO established in 2015 and headquartered in Shanghai, listed on HKSE	CDMO Service	Since 2017	Within 20 days	6,466	6.3
Supplier A	A leading CRO established in 2004 and headquartered in Hangzhou, dual listed on SZSE and HKSE	CRO Service	Since 2022	Within 30 days	4,858	4.7

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<u>Supplier</u>	<u>Supplier background</u>	<u>Service purchased</u>	<u>Year(s) of business relationship</u>	<u>Credit term granted</u>	<u>Purchase amount</u>	<u>% of total purchases</u>
<i>(RMB'000)</i>						
Supplier D	A leading preclinical services provider established in 2017 and headquartered in Chengdu	Preclinical Service	Since 2024	Within 30 days	4,146	4.0
Shanghai Langjing Biotechnology Co., Ltd. (上海朗晶生物科技有限公司)	A leading preclinical CRO established in 2019 and headquartered in Shanghai	CRO Service	Since 2019	Within 60 days	3,543	3.4
					<u>33,768</u>	<u>32.8</u>
<i>For the year ended December 31, 2024</i>						
Tarlead Biotechnology (Suzhou) Co., Ltd. (泰澧生物技術(蘇州)有限公司)	A leading CDMO established in 2022 and headquartered in Shanghai	CDMO Service	Since 2023	Within 15 business days	14,093	15.4
DMed Biopharmaceutical Company Limited (締脈生物醫藥科技(上海)有限公司)	A leading CRO established in 2016 and registered in Shanghai	CRO Service	Since 2020	Within 30 days	8,267	9.0
Supplier A	A leading CRO established in 2004 and headquartered in Hangzhou, dual listed on SZSE and HKSE	CRO Service	Since 2022	Within 30 days	7,278	8.0
Shanghai Langjing Biotechnology Co., Ltd. (上海朗晶生物科技有限公司)	A leading preclinical CRO established in 2019 and headquartered in Shanghai	CRO Service	Since 2019	Within 60 days	5,139	5.6
Supplier B	A leading CRO, established in 1996 and headquartered in Durham, North Carolina, the U.S., publicly listed on the Nasdaq	CRO Service	Since 2018	Within 30 days	5,036	5.5
					<u>39,813</u>	<u>43.5</u>

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<u>Supplier</u>	<u>Supplier background</u>	<u>Services purchased</u>	<u>Year(s) of business relationship</u>	<u>Credit term granted</u>	<u>Purchase amount</u>	<u>% of total purchases</u>
<i>(RMB'000)</i>						
<i>For the year ended December 31, 2023</i>						
Supplier B	A leading CRO, established in 1996 and headquartered in Durham, North Carolina, the U.S., publicly listed on the Nasdaq	CRO Service	Since 2018	Within 30 days	39,280	27.5
DMed Biopharmaceutical Company Limited (締脈生物醫藥科技(上海)有限公司)	A leading CRO established in 2016 and registered in Shanghai	CRO Service	Since 2020	Within 30 days	16,024	11.2
Supplier C	A CRO established in 2011 and headquartered in Shanghai	CRO Service	Since 2020	Within 30 days	15,157	10.6
Supplier A	A leading CRO established in 2004 and headquartered in Hangzhou, dual listed on SZSE and HKSE	CRO Service	Since 2022	Within 30 days	10,614	7.4
Tarlead Biotechnology (Suzhou) Co., Ltd. (泰禮生物技術(蘇州)有限公司)	A leading CDMO established in 2022 and headquartered in Shanghai	CDMO Service	Since 2023	Within 15 business days	7,857	5.5
					<u>88,933</u>	<u>62.3</u>

During the Track Record Period, none of our five largest suppliers was a related party to us. None of our Directors or their associates or, to the knowledge of our Directors, any Shareholder with over 5% of the share capital of our Company has any interest in any of our five largest suppliers during the Track Record Period.

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Raw Materials

During the Track Record Period, we have procured raw materials for the pilot manufacturing of our drug candidates for clinical trials from suppliers in China. The principal raw materials that we used include medium and filter materials, among others. As manufacturing was outsourced to CDMOs, the raw materials used were mainly platform materials integrated into the production processes of these outsourcing partners and managed under their quality control policies, with key materials selected based on process development data and subject to our regular audits. We select our suppliers by considering cost and their capability, quality, reputation, delivery and regulatory compliance.

Our principal raw materials are generally readily available in the market through a number of suppliers. We believe we have alternative sources for our principal raw materials with comparable quality and pricing. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material shortage or delay in the supply of raw materials. During the Track Record Period and up to the Latest Practicable Date, we did not experience any significant increases in the prices of our major raw materials or fluctuations in raw material costs which had a material adverse impact on our results of operations. See “Risk Factors — Risks Relating to Our Reliance on Third Parties — We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels.”

CUSTOMERS

During the Track Record Period, we had only four customers, Vignette Bio, Inc. (“**Vignette**”), Candid, Almirall and Juri. In 2024, we received non-refundable upfront payments from Vignette and Candid and also generated revenue from provision of research services under the Candid Agreement. In the nine months ended September 30, 2025, we received upfront payment from Juri, upfront and milestone payment from Almirall and generated revenue from provision of research services under the Candid Agreement. See “— Material Collaboration and Licensing Arrangements — License Agreement with Juri on KLK2/CD3 TCE Assets”, “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid for EMB-06”, “— Material Collaboration and Licensing Arrangements — License and Collaboration Agreement with Candid to Discover and Develop Multi-specific Antibody Assets” and “Material Collaboration and Licensing Agreements — Option and Evaluation Agreement with Almirall” for more details. We did not generate any revenue in 2023.

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The following table sets forth details of our customers in the indicated period:

<u>Customer</u>	<u>Customer background</u>	<u>Services purchased</u>	<u>Years of business relationship</u>	<u>Revenue contribution</u>	<u>% of total revenue</u>
<i>(RMB'000)</i>					
<i>For the nine months ended September 30, 2025</i>					
Juri Biosciences, Inc.	A biotech portfolio company incubated by TCG Labs Soleil, with a focus on efficiently translating scientific insights into therapeutic solutions for patients facing serious diseases	License grant	Since 2025	71,534	78.0
Candid Therapeutics, Inc.	A clinical-stage biotechnology company focused on researching and developing T-cell engager antibodies for therapeutic uses, including for treatment of autoimmune diseases	License grant and research service	Since 2024	12,951	14.1
Almirall, S.A.	A Spanish pharmaceutical company focused on medical dermatology with headquarters in Barcelona and listed on the Madrid Stock Exchange under the ticker symbol ALM	License grant	Since 2024	7,201	7.9
Total				91,686	100.0
<i>For the year ended December 31, 2024</i>					
Vignette Bio, Inc.*	A clinical-stage company formed in 2024 and incubated by Foresite Labs, with a focus on innovative therapies to address immunology and inflammation associated diseases	License grant	Since 2024	428,694	93.4
Candid Therapeutics, Inc.	A clinical-stage biotechnology company focused on researching and developing T-cell engager antibodies for therapeutic uses, including for treatment of autoimmune diseases	License grant and research service	Since 2024	30,171	6.6
Total				458,865	100.0

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Note:

* Vignette Bio, Inc. was acquired by Candid Therapeutics, Inc. in September 2024.

COMPETITION

The market for biopharmaceutical industry and immuno-oncology solutions 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 information on the competitive landscape of our drug candidates, see “Industry Overview” in this document and “— Our Drug Candidates” in this section.

We believe that the primary competitive factors in our markets include the identification of promising targets, mechanisms, and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, manufacturing efficiency, and commercialization development. We expect the competition will become more intensive in the future as additional players enter the segments. Any drug candidates successfully developed and commercialized by us will compete with existing drugs or any new drugs that may become available in the future. For potential impact of market competition, please see “Risk Factors — Risks Relating to the Research and Development of Our Drug Candidates — We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our drug candidates.”

EMPLOYEES

As of September 30, 2025, we had a total of 72 full-time employees, a majority of whom were based in China. The following table sets forth a breakdown of our employees categorized by function as of September 30, 2025:

Function	Number	Percentage (%)
Research and clinical development	45	62.5
CMC and quality control	1	1.4
Business development and intellectual property	5	6.9
General and administrative	21	29.2
Total	72	100.0

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We recruit employees primarily through online recruitment agencies, social media platforms, and employee and headhunter referrals. We enter into standard labor, confidentiality, and intellectual property ownership agreements with our employees to protect proprietary information and secure company rights to work-related innovations. We provide our employees with a diverse array of professional development opportunities and foster a performance-driven environment, including pre-job training, on-the-job practice, cross-departmental rotation, and special skills training.

We are committed to ensuring that working conditions throughout our business network are safe and that employees are treated with care and respect. We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurance, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government regulations from time to time. Our compensation package also comprises supplementary commercial insurance, annual physical examination, transportation and meal allowances and holiday benefits. In addition, we offer a range of incentive schemes designed to attract, retain and motivate employees, including performance-based bonuses, retention and R&D milestone awards.

During the Track Record Period, we were not in strict compliance with the requisite contribution requirements of social insurance in relation to some of our foreign employees, which we believe will not bring any material adverse effect to our operations or financial position. In 2023, 2024 and the nine months ended September 30, 2025, the shortfall of social insurance contributions amounted to RMB0.4 million, RMB0.4 million and RMB0.3 million, respectively. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. The credit report issued by the relevant authority revealed no record of violation of the relevant laws and regulations in the area of social security. As advised by our PRC Legal Advisor, based on the foregoing and assuming that (a) there are no material changes to the current social insurance-related laws, regulations, policies, or to the enforcement and supervision requirements imposed by the relevant authorities, and (b) no foreign employees report or complain to the relevant authorities about the non-payment of social insurance contributions on their behalf, if we can rectify the aforementioned issue or make up the full amount of such contributions for them as required by the relevant authorities within a prescribed period, the likelihood that we will be subject to administrative penalties by the relevant authorities for not making contributions for some foreign employees in social insurance, thereby causing material adverse effects on our operations, is relatively remote. As a result, we had not made any provision for the shortfall in our social insurance during the Track Record Period and up to the Latest Practicable Date.

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Pursuant to the Article 19 of the New Judicial Interpretation, if an employer and an employee agree or the employee undertakes that social insurance contributions are not required to be paid, the People’s Court shall deem such agreement or undertaking invalid, and where an employer fails to pay social insurance contributions in accordance with the law, and the employee requests to terminate the labor contract and claims economic compensation from the employer in accordance with the PRC Labor Contract Law, the People’s Court shall support such claims. See “Regulatory Overview — Regulations on Employment and Social Welfare” for details. Our directors are of the view that the New Judicial interpretation would not have a material adverse effect on our business, financial condition or results of operations, based on the following considerations: (i) as advised by our PRC Legal Advisor, upon its implementation, the New Judicial Interpretation will not affect the compliance status of our social insurance contributions, (ii) it will not influence the assessment of any contribution shortfalls or increase our exposure to penalties, and (iii) shortfall in social insurance contributions is relatively small.

We have taken the following internal control measures to ensure compliance with the social insurance contribution requirements under the relevant laws and regulations to the extent practicable:

- *Human Resource Management Policies.* We have implemented an *Employee Handbook* which explicitly requires social insurance and housing provident fund contributions to be made in full in accordance with applicable local requirements.
- *Training.* We have adopted a legal and regulatory training plan to strengthen the training of our employees on various topics in relation to compliance with labor law.
- *Increasing Awareness of Developments in Law.* We closely monitor and stay informed of the latest developments in PRC laws and regulations relating to social insurance and housing provident funds to ensure timely alignment of our internal policies and practices.
- *Internal Control Measures.* We have adopted a *Compliance Manual*, which requires our internal control team to conduct quarterly self-assessments and reporting on our adherence to applicable laws and regulations in relation to social insurance and housing provident funds.
- *Consultation.* We consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to keep us abreast of relevant regulatory developments; and actively communicate with relevant social insurance and housing fund local authorities to ensure we have the most updated information about the relevant laws and regulations concerning social insurance and housing provident fund.

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If the relevant authorities order us to pay the shortfall in our social insurance or take any rectification measures in accordance with applicable laws and regulations, we undertake that we will rectify as requested as soon as practicable.

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

PROPERTIES

We are headquartered in Shanghai. We currently do not own any land use rights or properties. As of the Latest Practicable Date, we leased one property with a gross floor area of approximately 2,565.67 sq. m. from independent third parties as our office premises and R&D center in the PRC.

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

<u>Usage</u>	<u>Location</u>	<u>Gross Floor Area</u>	<u>Lease Term</u>
		<i>(sq. m.)</i>	
Office premises and R&D. . .	Shanghai	2,565.67	60 months

According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to our interests in land or buildings, for the reason that, as of the date of the most recent audited consolidated balance sheet of our Group, the property leased by us did not have a carrying amount of 15% or more of our consolidated total assets.

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AWARDS AND RECOGNITIONS

The table below sets forth the major awards and recognition we received as of the Latest Practicable Date:

Year of Grant	Award/Recognition	Issuing Authority
2025	Top 100 China Pharmaceutical Innovative Seed Enterprises (中國醫藥創新種子企業100強)	Healthcare Executive (E藥經理人)
2025	2025 Chinese Healthcare Front-Runners Top 100 – Outstanding Leaders (2025中國生物醫藥領跑者100 –卓越領袖)	Shanghai Center of Biomedicine Development (上海市生物醫藥科技產業促進中心)
2025	New Drug Founder “Most Innovative Award” (新藥創始人(最具創新力獎))	Organizing Committee of the “Decade” Event for New Drug Founders (新藥創始人“拾年”活動組委會)
2025	2025 Zhangjiang Innovative Pharmaceutical Enterprises Global Competitiveness TOP15 (2025張江創新藥企全球競爭力TOP15)	Zhangjiang International Life Science Innovation Summit & PharmCube (張江生命科學國際創新峰會&醫藥魔方)
2024	2024 China Innovative Drug Business Development TOP15 (2024中國創新藥商務拓展TOP15)	PharmCube (醫藥魔方)
2023	2023 Top 30 Most Innovative Chinese Antibody Therapeutics Enterprises (2023年度中國抗體藥物企業創新力TOP30排行榜)	Menet (米內網)
2023	2023 China Biopharmaceutical Industry Innovation Rank — Top 10 Most Influential Antibody Biotech Companies (2023中國生物醫藥產業價值榜—最具成長性抗體藥企業TOP10)	Huayi Rank (華醫榜)

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Year of Grant	Award/Recognition	Issuing Authority
2022	2022 Top 30 Most Innovative Chinese Antibody Therapeutics Enterprises (2022年度中國抗體藥物企業創新力TOP30排行榜)	Menet (米內網), Expert Committee for Top 100 Innovative Chinese Biopharmaceutical Enterprises Lists (中國生物醫藥企業創新力百強系列榜單專家委員會)
2022	2022 China Biopharmaceutical Industry Innovation Rank — Top 20 Most Influential Antibody Biotech Companies (2022中國生物醫藥產業價值榜—最具影響力抗體藥企業TOP20)	China Bio-Pharm Partnering Forum Committee (中國生物醫藥創新合作大會組委會)
2021	2021 Top 10 Chinese Bispecific Antibody Drug Companies (2021年中國雙抗藥物十大領軍企業)	China Biopharmaceutical Innovation Summit Forum (中國生物醫藥創新高峰論壇)
2020	2020 Top 30 Most Innovative Chinese Antibody Therapeutics Enterprises (2020年度中國抗體藥物企業創新力TOP30排行榜)	Menet (米內網), Expert Committee for Top 100 Innovative Chinese Biopharmaceutical Enterprises Lists (中國生物醫藥企業創新力百強系列榜單專家委員會)
2019	Hurun China Future Unicorns 2019 Q2 (2019二季度胡潤榜中國潛力獨角獸)	Hurun Research Institute (胡潤研究院)
2019	Recognition of Multinational Corporation R&D Centers (跨國公司研發中心證書)	Shanghai Municipal Commission of Commerce (上海市商務委員會)
2019	2019 Top 50 Most Innovative Chinese Biopharmaceutical Companies (2019中國生物醫藥最具創新力企業50強)	Star Glory Research Institute (星耀研究院)

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Year of Grant	Award/Recognition	Issuing Authority
2019	2019 Cortellis Top APAC Pharmaceutical Innovator (亞太地區TOP生物創新藥企)	Clarivate Analytics (科睿唯安)
2019	2019 Insight into Zhangjiang Quasi-Unicorn Companies (2019洞見張江准獨角獸企業)	Zhangjiang Vπ (張江Vπ)
2018	Jinji Lake Talent Program — Leading Scientific and Technological Talent (金雞湖人才計畫科技領軍人才)	The Communist Party of China Suzhou Industrial Park Working Committee (中共蘇州工業園區工作委員會) and Suzhou Industrial Park Administrative Committee (蘇州工業園區管理委員會)
2017	2017 Fortune International Brainstorm Tech Forum Innovation Award (2017年財富國際科技頭腦風暴大會創新大獎)	Fortune International (財富國際); GAC Group (廣汽集團)
2017	The 6th China Innovation and Entrepreneurship Competition — First Prize in the Biomedicine Industry Startup Group (第六屆中國創新創業大賽生物醫藥行業初創組一等獎)	China Innovation and Entrepreneurship Competition Organizing Committee (中國創新創業大賽組委會)

ENVIRONMENTAL, SOCIAL, HEALTH AND SAFETY MATTERS

We acknowledge our environment protection and social responsibilities and are aware of the environmental, energy, climate-related and workplace safety issues that may impact our Group’s business operation. We are committed to complying with environmental, social and governance (“ESG”) reporting requirements upon [REDACTED].

Our Board has overall responsibility for (i) overseeing and determining our Group’s environmental, social, and climate-related risks and opportunities that impact our Group, (ii) establishing ESG related targets of our Group, (iii) adopting the ESG related policies, and (iv) reviewing our Group’s performance in ESG matters.

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Environmental Protection

We strive to operate our facilities in a manner that protects the environment. We do not operate in a highly polluting industry, but the manufacturing process of our drug candidates for clinical trials and research involves the use of hazardous, flammable and toxic materials, and may exhaust gas and generate wastewater, solid waste, and other hazardous waste.

To ensure compliance with national, industrial, and local environmental standards, laws, regulations, and policies, we have implemented internal policies for environmental risk prevention. These policies include: (i) strict adherence to cGMP regulations and relevant pollutant emissions standards in the industry; (ii) implementing stringent guidelines of procedures for operating in our laboratory facilities, covering solid waste disposal, wastewater and exhaust gas treatment, and management of chemicals that are hazardous, flammable, explosive and highly toxic; and (iii) conducting periodic environmental assessments on exhaust gas emissions, hazardous waste disposal, and wastewater emissions.

During the Track Record Period and up to the Latest Practicable Date, we had not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

We continuously monitor and strive to reduce hazardous waste production. The wastewater and exhaust gas generated in our R&D process are pretreated by us before being discharged. Our efforts have led to a decrease in wastewater discharge levels related to research and testing from approximately 1.75 tons in 2023 to approximately 1.72 tons in 2024. Similarly, solid waste transferred to third parties decreased from approximately 3.29 tons in 2023 to approximately 3.18 tons in 2024. For hazardous wastes (including medical waste) generated from R&D activities, we engage qualified third parties for disposal. In the years ended December 31, 2023 and 2024 and the nine months ended September 30, 2025, we incurred costs of approximately RMB34.5 thousand, RMB69.2 thousand and RMB26.4 thousand, respectively, for hazardous waste disposal. These third-party service providers operate in accordance with relevant governmental laws and regulations. We are committed to ongoing efforts to protect the ecological environment during our business operations, aiming to minimize adverse environmental impacts.

Resource Consumption and Emissions

The waste we produce is divided into hazardous waste, such as chemical waste and non-hazardous waste, such as waste from general office operations. Our greenhouse gas emissions primarily consist of Scope 1, Scope 2 and Scope 3 emissions. Scope 1 emissions are largely limited to small-scale emissions related to R&D processes and facilities. Scope 2 emissions primarily include the indirect emissions associated with purchased electricity to support our operations. Scope 3 emissions, which involve indirect emissions mainly consist of indirect emissions outside of Scope 2 emissions that occur in our value chain. As a clinical-stage biotechnology company, our operations are currently focused on R&D activities,

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resulting in minimal greenhouse gas emissions across Scope 1, Scope 2 and Scope 3. In pursuit of our sustainable development objectives, we rigorously oversee our environmental protection performance across various domains, including resource efficiency and energy consumption. We closely monitor our electricity and water consumption levels and actively implement strategies to enhance energy efficiency and promote water conservation:

	Year Ended December 31,		Nine Months Ended September 30,
	2023	2024	2025
Resource consumption			
Electricity (<i>MWh</i>)			
– Total amount	603.7	593.9	511.6
– Intensity* (<i>MWh/RMB million</i>)	3.3	4.8	5.3
Water (<i>tons</i>)			
– Total amount	741	1,003	754
– Intensity* (<i>t/RMB million</i>)	4.0	8.2	7.8
Emission			
Hazardous solid waste (<i>ton</i>)			
– Total amount	3.29	3.18	1.88
– Intensity* (<i>ton/RMB million</i>)	0.02	0.03	0.02
Wastewater related to research and testing (<i>ton</i>)			
– Total amount	1.75	1.72	1.57
– Intensity* (<i>ton/RMB million</i>)	0.01	0.01	0.02

Note:

* Calculated as the total amount of resource consumption or emission divided by the R&D expense of the respective year/period.

Goals, Targets

The ESG committee will set targets for each material key performance indicator at the beginning of each financial year in accordance with the disclosure requirements under Appendix C2 to the Listing Rules and any other relevant rules and regulations after [REDACTED]. Relevant targets of the material key performance indicators will be reviewed annually to ensure that they are still suitable for our needs. When setting the targets for environment-related KPIs, we will take into account our respective consumption or emission levels during the Track Record Period, and consider our future business expansion in a comprehensive and prudent manner, with a view to crafting a balance between business growth and environmental protection and achieving sustainable development. Our current objective is to establish a robust ESG governance mechanism and system for our Company. With the expansion of our business and commercialization of our drug candidates in the future, we endeavor to curb the increase in our resource consumption and emissions and aim to keep them

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relatively stable. The historical energy consumption data from the Track Record Period will serve as a foundational basis for devising pertinent energy reduction strategies and establishing suitable reduction targets for the future. Our aim is to reduce electricity and water consumption and wastewater related to research and testing disposal by around 5.0% by 2027. This goal reflects our endeavor to strike a balance between advancing our R&D and manufacturing endeavors over the next three years, while also upholding our environmental commitment. We plan to achieve this by optimizing processes to maximize electricity utilization and minimize water wastage in our daily operations.

Aligned with the ESG evaluation system standards in China and industry best practices, we are committed to mitigating or minimizing the adverse environmental impacts resulting from our operations. With the expansion of our business and anticipated commercialization of our drug candidates, we expect our resource consumption to increase. However, we have developed, and will continue to implement, environmental management plans aimed at continually enhancing our energy consumption efficiency and ensuring compliance with all governmental environmental regulations and requirements. Our current objective is to establish a robust ESG governance mechanism and system for our Company. The historical energy consumption data from the Track Record Period will serve as a foundational basis for devising pertinent energy reduction strategies and establishing suitable reduction targets for the future.

To achieve our goal of sustainable development, we have already implemented the following environmentally friendly measures:

- promote environmental awareness among all staff by encouraging them to minimize paper waste and conserve water and electricity resources, such as placing water-saving or power-saving signs in prominent areas to capture attention and foster our employees' commitment to environmental protection;
- regularly conducting inspections of our equipment in laboratories facilities to check for abnormal conditions, and make prompt report to avoid potential damages;
- carrying out manual check after shift to eliminate unnecessary lighting; and
- promoting recycling schemes, seeking alternative ways of disposing of and reducing waste in environmental-friendly ways.

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations.

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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 hurricanes 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 drugs and 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.

We have effective supplier management in place, as we have established detailed internal rules governing the selection of CROs. When research services are needed, procurement requests are initiated by the R&D department. The R&D department evaluates CRO candidates based on project requirements, qualifications, goodwill and reputation, and other factors, and requests specific documentation and data to ensure alignment with our Group’s policy. After the R&D department preliminarily selects CROs, service proposals are submitted for approval by department heads and the CEO of our Company. Once approved, CROs are engaged in accordance with our Group’s service procurement policy. For further detail of our selection criteria of CROs, see “— Research and Development — Clinical Development — Collaborations with CROs.”

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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:

- have established guidelines governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes;
- provide regular safety awareness training to our employees, including sessions on fire control and safety; and
- conduct regular fire safety inspections, ensure the maintenance of firefighting equipment, and organize routine emergency drills to prepare employees for emergency situations.

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 September 30, 2025, over 60% 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.

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 cover adverse events in our clinical trials, and we also maintain commercial life and medical insurance for our employees. We maintain social insurance for our employees in accordance with relevant PRC laws and regulations. We believe that our insurance coverage is adequate to cover our key assets, facilities, and liabilities.

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PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, as advised by our PRC Legal Advisor, we had obtained all material licenses and permits required for our business operations in the PRC, and such business licenses had remained in full effect. For more details regarding the laws and regulations to which we are subject, see “Regulatory Overview” in this document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. During the Track Record Period and up to the Latest Practicable Date, no material unexpected or adverse changes that could adversely affect the maintenance and renewal of our material licenses, permits, approvals and certificates had occurred since the dates of issue of the relevant regulatory approvals for our business operation.

LEGAL PROCEEDINGS AND COMPLIANCE

As of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the 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, 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.”

We are of the view that, 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. Our Directors confirmed that, during the Track Record Period and up to the Latest Practicable Date, 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.

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Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global biopharmaceuticals markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other biopharmaceutical companies. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit 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 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; (iii) analyzing material findings related to internal control and assessing the measures taken by management; and (iv) supervising potential misconduct by employees regarding internal control and establishing procedures to investigate and address complaints related to internal control within our Company.
- 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 (vi) 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

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categorization of all key risks that could impact their objectives; (iii) prepare an annual risk management report for review by our chief executive officer; (iv) continuously monitor key risks pertinent to their operations or functions; (v) implement appropriate risk responses when necessary; and (vi) 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 February 1, 2024 to January 31, 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 April 2025, 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.

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 “— Environmental, Social, Health and Safety Matters” in this section. We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports any weaknesses identified to our management and Audit Committee, and follows up on the rectification actions.

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- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our new employees are required to attend compliance training programs soon after onboarding and must confirm their understanding of the compliance issues addressed by our employee handbook. 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 will establish 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.