

REGULATORY OVERVIEW

This section sets out an overview of certain laws and regulations relevant to our business and operations.

PHARMACEUTICAL REGULATORY SYSTEM OF THE PRC

The major regulatory authorities of pharmaceutical industry in the PRC include the NMPA, the NHC, and the National Healthcare Security Administration.

The NMPA assumes the responsibilities for pharmaceutical supervision of China Food and Drug Administration (“CFDA”), its predecessor, as the principal pharmaceutical regulatory authority in charge of the pharmaceutical registration and supervision, including non-clinical research, clinical trial, marketing approval, production and circulation.

The NHC is the chief healthcare regulator of the PRC, which is primarily responsible for drafting national healthcare policies, regulating public health, medical services and health contingency system, coordinating the implementation of healthcare reform and overseeing the operation of medical institutions and practice of medical personnel.

The National Healthcare Security Administration (an authority established in May 2018 in accordance with the Institutional Reform Program of the State Council) is responsible for (i) drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; (ii) administering healthcare fund; (iii) formulating a uniform medical insurance catalogue and payment standards on drugs, medical consumables and healthcare services; and (iv) formulating and administering the bidding and tendering policies for drugs and medical consumables.

PRC LAWS AND REGULATIONS RELATING TO DRUGS

Drug Administration Laws and Regulations

The PRC Drug Administration Law (中華人民共和國藥品管理法) (“**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (“NPCSC”) on September 20, 1984, and amended on February 28, 2001, December 28, 2013, April 24, 2015, and August 26, 2019, as well as the Implementing Rules for the PRC Drug Administration Law (中華人民共和國藥品管理法實施條例) (“**Implementing Rules for the Drug Administration Law**”) issued by the State Council on August 4, 2002, and amended on February 6, 2016 and March 2, 2019 and January 16, 2026 have together laid down the legal framework for the administration of drugs, including the research, development, manufacturing and business operation for new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical operating enterprises, and medicinal preparations of medical institutions, along with the development, research, production, distribution, packaging, pricing and advertisements of drugs.

Non-Clinical Research and Animal Testing

The State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局) (“SAMR”) requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration (藥品註冊管理辦法), which was issued by the SAMR on January 22, 2020 and became effective on July 1, 2020, non-clinical drug safety evaluation studies shall comply with the good laboratory practice (“GLP”) for Non-clinical Laboratory Studies (藥物非臨床研究質量管理規範). The latest GLP has been implemented by the CFDA since September 1, 2017 to improve the quality of non-clinical research. Pursuant to the Measures for Administration of Certification of the GLP for Non-clinical Laboratory Studies (藥物非臨床研究質量管理規範認證管理辦法) promulgated on January 19, 2023 and implemented since July 1, 2023 by the NMPA, applying for the GLP certification is required for institutions that intend to conduct non-clinical safety evaluation studies in the PRC used for drug registration applications. The NMPA is in charge of the administration of the GLP certification

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nationwide, while the provincial medical products administrative authorities are responsible for the daily supervision and administration of non-clinical safety evaluation studies institutions within the administrative region. The GLP Certificate will be issued by the NMPA with its approval if the relevant requirements for the GLP are satisfied by the applicant. The valid period for the GLP certificate lasts for 5 years. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations. Pursuant to the Administrative Regulations on Experimental Animals (實驗動物管理條例) issued by the State Science and Technology Commission on November 14, 1988, and latest amended on March 1, 2017 by the State Council, the Administrative Measures on Good Practice of Experimental Animals (實驗動物質量管理辦法) jointly issued by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (實驗動物許可證管理辦法(試行)) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and implemented since January 1, 2002, using and breeding experimental animals shall be subject to certain rules, and performing experiments on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Approval of Clinical Trials

Pursuant to the Administrative Measures for Drug Registration, an applicant that applies for a drug clinical trial after completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, shall submit relevant research materials according to the requirements for application materials. The application materials shall be accepted if they are deemed acceptable upon formal examination. The CDE shall organize pharmaceutical, medical and other technicians to review the accepted application for the drug clinical trial. A decision on approval or non-approval of the application for clinical trials of drugs shall be made within 60 days from acceptance of application, and the applicant shall be notified of the examination and approval outcome through the CDE website; where the applicant is not notified within the stipulated period, the application shall be deemed approved, and the applicant may conduct clinical trial of drugs in accordance with the submitted scheme.

According to the Circular on Drug Clinical Trial Information Platform (關於藥物臨床試驗信息平台的公告) issued by the CFDA on September 6, 2013, all clinical trials approved by the NMPA and conducted in the PRC shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Public Information Platform. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of the drug clinical trial to obtain an exclusive trial registration number and complete the subsequent information registration before the first participant is enrolled in the trial.

Phases of Clinical Trials and Communication with the CDE

Pursuant to the Drug Administration Law (藥品管理法), drug clinical trials shall be carried out in a clinical trial institution with corresponding conditions. The conditions that clinical trial institution should satisfy shall mainly comply with the relevant requirements of Administrative Regulations for Drug Clinical Trial Institutions (藥物臨床試驗機構管理規定), which came into effect on December 1, 2019. Such drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The NMPA is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

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According to the Administrative Measures for Drug Registration, based on the drug’s characteristics and the purpose of research, clinical trials of drugs consist of phase 1, 2, 3 and 4 clinical trials, as well as the bioequivalence trials, contents of which include clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing research. Clinical trials shall be conducted in accordance with the provisions of the PRC GCP, including the preparation for clinical trials, clinical trial protocols, responsibilities of sponsors and investigators, and protection of subjects, etc. Pursuant to the Administrative Measures for Communication on Drug Development and Technical Reviews (藥物研發與技術審評溝通交流管理辦法) issued by the CDE on April 3, 2026, during the research and development, and application for registration stages of innovative drugs, the applicant may propose communication sessions with the CDE. The forms of communication can be face-to-face conference, video conference, telephone conference or written replies. The communication sessions are classified into three types. Type I sessions are held to address the material safety issues encountered in the clinical trials of drugs and the significant technical issues in the research and development process of breakthrough therapeutic drugs. Type II sessions are held during the key research and development stages of drugs, mainly including the sessions held prior to the application of IND, the sessions held upon completion of phase 2 clinical trials and prior to commencement of phase 3 clinical trials of new drugs, the sessions held prior to application for marketing approvals of new drugs, and the risk evaluation and control sessions. Type III sessions are those sessions not falling into the categories of Type I or II sessions.

International Multi-Center Clinical Trial

Pursuant to the International Multi-Center Clinical Trial Guidelines (Trial) (國際多中心藥物臨床試驗指南(試行)) issued by the CFDA on January 30, 2015 and effective from March 1, 2015, applicants may simultaneously conduct clinical trials in different centers of multiple regions using the same clinical trial protocol, or conduct regional clinical trials simultaneously in multiple centers in different countries within a certain region using the same protocol. Where the data derived from the international multi-center clinical trials are to be used for application for a drug registration in the PRC, it shall satisfy the requirements for clinical trials set forth in the Administrative Measures for Drug Registration. Where the applicant plans to conduct the international multi-center clinical trials in the PRC, it shall comply with the Drug Administration Law, the Implementing Rules for the Drug Administration Law and the Administrative Measures for Drug Registration and other relevant laws and regulations, to carry out the PRC GCP with reference to internationally recognized principles such as the ICH-GCP, and to meet the requirements of the laws and regulations of the relevant countries at the same time. In addition, the NMPA issued the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (接受藥品境外臨床試驗數據的技術指導原則) on July 6, 2018 to guide work related to the acceptance of overseas clinical trial data as clinical evaluation reference by the applicant applying for the registration of drugs in the PRC.

Registration and Application of New Drugs

According to the Administrative Measures for Drug Registration, the drug registration administration shall be categorized into traditional Chinese drugs, chemical drugs and biological products; among them, the registration of chemical drugs shall be categorized into innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

Pursuant to the Reform Plan for Registration Category of Chemical Medicine (化學藥品註冊分類改革工作方案) issued by the CFDA on March 4, 2016, new registration of chemical drugs are divided into 5 categories: (i) Category 1: innovative drugs that have not been marketed in the PRC or abroad and that contains new compounds with clear structure, pharmacological effects and clinical value, a category into which our product candidate fall; (ii) Category 2: improved new drugs that have not been marketed in the PRC or abroad with optimization in structure, dosage form, prescription technology, route of drug administration and indications on the basis of known active ingredients as well as obvious clinical advantages; (iii) Category 3: drugs imitated by domestic applicants which are marketed overseas while originator’s drugs are not marketed in the PRC. Such

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drugs should possess quality and efficacy in line with that of the originator’s drugs (i.e. the first drugs approved to be marketed in the PRC or overseas with complete and sufficient safety and efficacy data to serve as the basis for its launch); (iv) Category 4: drugs imitated by domestic applicants while originator’s drugs have been marketed in the PRC. The quality and efficacy of such drugs should be consistent with that of the originator’s drugs; and (v) Category 5: drugs which have been marketed abroad with the applications to be marketed in the PRC. Among them, the reporting procedures for Category 1 and 2 shall comply with those for new drugs; the reporting procedures for Category 3 and 4 shall be in accordance with those for generic drugs; and the reporting procedures for Category 5 shall be reported pursuant to the procedures for imported drugs.

According to the Registration Classification of Chemical Drugs and the Reporting Information Requirements (化學藥品註冊分類及申報資料要求) issued by the NMPA on June 29, 2020 with implementation of the Registration Classification of Chemical Drugs from July 1, 2020, the registration of chemical drugs is categorized into innovative drugs, improved new drugs, generic drugs, and chemical drugs marketed abroad only. The Registration Classification of Chemical Drugs and the Reporting Information Requirements reaffirmed the classification principles for chemical drugs set forth by the Reform Plan for Registration Classification of Chemical Drugs (化學藥品註冊分類改革工作方案) and made further adjustments to the chemical drugs subclassifications of Category 2 and 5 among which as well as elaboration regarding the quality and efficacy requirements for generic drugs in Category 3 and 4; in addition, it is also proposed the registration requirements and reporting information requirements for various types of chemical drugs.

According to the Administrative Measures for Drug Registration, the applicant may submit an application for permission of the drugs registration for marketing (“**New Drug Application**”) upon determining quality standards after completion of researches on pharmacy, pharmacology, toxicology, and clinical trials of drugs that support the registration of drugs for marketing and completing the commercial-scale production process verification and preparations for receiving on-site inspections. The New Drug Application shall be evaluated by the NMPA in accordance with applicable laws and regulations.

Accelerated Approval for Clinical Trial and New Drug Registration

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices (國務院關於改革藥品醫療器械審評審批制度的意見) issued by the State Council on August 9, 2015 has established a reform framework of the evaluation and approval system for drugs and medical devices, and specified the tasks of enhancing the standards of approval for, among others, drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs.

The Announcement on Several Policies on Drug Registration Review and Approval (關於藥品註冊審評審批若干政策的公告) issued by the CFDA on November 11, 2015 has provided fast-track clinical trial approvals and drug registration pathways for the following new drug applications: (i) registration of innovative new drugs treating HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of geriatric drugs and drugs treating diseases specially or commonly contracted by the senior population; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology or innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities’ onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (viii) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

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On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation of Drugs and Medical Devices (關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見), aiming to simplify the clinical trial procedures and shorten the time. For new drugs and medical devices urgently needed in clinical practice and drugs and medical devices used for the treatment of rare diseases, the evaluation and approval procedures for marketing shall be accelerated.

Furthermore, according to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (關於優化藥品註冊審評審批有關事宜的公告) jointly issued by the NMPA and the NHC on May 17, 2018, the drug approval process shall be further streamlined and expedited.

Pursuant to the provisions of the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (突破性治療藥物審評工作程序(試行)) issued by the NMPA on July 7, 2020, during the clinical drug trials, the applicant is allowed to apply for the breakthrough therapeutic drug procedure during phase 1 and phase 2 clinical trials and normally no later than the commencement of phase 3 clinical trials for the innovative or improved drugs etc. which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over existing treatment approach.

The Administrative Measures for Drug Registration has integrated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduced four procedures for expedited marketing registration of drugs, which are procedures for breakthrough therapeutic drugs, procedures for conditional approval, procedures for prioritized review and approval, and procedures for special examination and approval:

Procedures for breakthrough therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for breakthrough therapeutic drugs.

Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.

Procedures for prioritized review and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for breakthrough therapeutic drug; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances of prioritized review promulgated by the NMPA.

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Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency.

Marketing Authorization Holder (“MAH”) System

Pursuant to Drug Administration Law, the drug marketing authorization holder system has been implemented for drug management in the PRC. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate, which is responsible for the safety, efficacy and controlled quality of medicine during the whole process of drug development, production, operation and utilization processes in accordance with laws. The marketing authorization holders shall be liable for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the pharmaceuticals. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs.

The drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs; they may sell drugs with a drug registration permit on their own or through entrusting qualified drug operating enterprises. Blood products, anesthetics, psychotropic drugs, toxic drugs for medical use and pharmaceutical precursor chemicals are in principle not allowed to be produced through entrustment.

The drug marketing authorization holders shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the management of drug quality; the drug marketing authorization holders shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise their continuous quality assurance and control capabilities. The drug marketing authorization holders, drug manufacturers, drug distributors and medical institutions shall establish and implement a drug traceability system, provide traceability information in accordance with regulations and ensure that drugs are traceable.

The implementation and oversight of the MAH system involve a multi-tiered regulatory framework in the PRC, with the following key authorities:

- **NMPA:** As the core regulatory authority for the MAH system, the NMPA is responsible for the issuance of Drug Registration Certificates, the qualification review of MAHs, and full lifecycle supervision. Its mandates include the approval of clinical trials, inspection of manufacturing sites, and monitoring of adverse drug reactions. The NMPA exercises these powers in accordance with the Drug Administration Law and the Administrative Measures for Drug Registration.
- **CDE:** The CDE is responsible for conducting specific technical reviews related to MAH applications. This includes the evaluation of drug registration submissions (such as Investigational New Drug and New Drug Application filings), the review of clinical trial protocols, and providing technical guidance and communication to applicants.
- **Provincial drug regulatory department:** These local authorities are responsible for territorial supervision. Their duties include overseeing Good Manufacturing Practice compliance of entrusted production enterprises within their jurisdictions, conducting routine inspections, and verifying reports of adverse drug reactions.

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Pharmacovigilance

Pursuant to the Pharmacovigilance Quality Control Specifications (藥物警戒質量管理規範) issued by the NMPA on May 7, 2021 and implemented from December 1, 2021, drug marketing authorization holders and drug registration applicants who are permitted to implement drug clinical trials shall establish the pharmacovigilance system to monitor, identify, evaluate and control adverse drug reactions and other drug-related harmful reactions through the effective operation and maintenance of the system. The drug marketing authorization holders shall initiate quality objectives for pharmacovigilance and establish quality assurance system for quality management on pharmacovigilance system and activities with an aim to consistently improve the efficiency of the system and ensure the compliance of the activities with the relevant laws and regulations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the pharmacovigilance activities. The drug marketing authorization holders shall complete the information registration in the National Adverse Drug Reaction Monitoring System within 30 days upon the date of obtaining the first drug approval document.

Filing for Gathering and Collection of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human Genetic Resources (人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南) promulgated by the Ministry of Science and Technology on July 2, 2015, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. The Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (關於優化人類遺傳資源行政審批流程的通知) on October 26, 2017, which became effective on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

According to the Regulation of the People’s Republic of China on the Management of Human Genetic Resources (中華人民共和國人類遺傳資源管理條例), as promulgated by the State Council on May 28, 2019, effective on July 1, 2019, and revised on March 10, 2024, in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without export of human genetic resources materials. However, the two parties should file the type, quantity and usage of the human genetic resources to be used with the competent health department under the State Council before clinical trials. On May 26, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (人類遺傳資源管理條例實施細則), which became effective from July 1, 2023, further specifying the requirements for the collection, preservation, use, and outbound offering of the human genetic resources in the PRC.

On October 17, 2020, the NPCSC promulgated the Biosecurity Law of the PRC (中華人民共和國生物安全法) (“**Biosecurity Law**”), which became effective on April 15, 2021 and was revised on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including epidemic control of human, animal and plant infectious diseases, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons. According to the Biosecurity Law, the high-risk and medium-risk biotechnology research and development activities shall be carried out by legal entities lawfully established in the PRC, and shall be approved or filed; the establishment of a pathogenic microbiology laboratory shall be lawfully approved or filed; the approval from the competent health department under the State Council is required for the following activities: (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human

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genetic resources of which the types and quantities are subject to provisions of the competent health department under the State Council, (ii) preserving human genetic resources of the PRC, (iii) using human genetic resources of the PRC to carry out international scientific research cooperation, or (iv) transporting, mailing or exiting human genetic resource materials of the PRC.

Drug Manufacturing License

According to the Drug Administration Law and the Implementing Rules for the Drug Administration Law, when engaging in pharmaceutical manufacturing activities, an enterprise must obtain a Drug Manufacturing License (藥品生產許可證) granted by the drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government at the place where the enterprise is located. No medicinal products shall be manufactured without a Drug Manufacturing License. The drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government shall organize acceptance inspection for an enterprise subject to the following conditions, and issue a drug manufacturing license if the acceptance inspection is passed: (i) it shall be staffed with legally certified pharmaceutical technical personnel, engineering technical personnel, as well as corresponding skilled workers; (ii) it shall have factory premises, facilities and a sanitary environment suitable for the drugs produced; (iii) it shall have institutions and personnel capable of managing and inspecting the quality of the drugs produced, as well as necessary instruments and equipment; and (iv) it shall have rules and regulations to ensure the quality of drugs. Each Drug Manufacturing License is valid for a period of five years. If an enterprise holding the Drug Manufacturing License needs to continue the manufacturing of drugs upon the expiration of the license, the enterprise should apply for renewal in compliance with the regulation of the drug regulatory authority under the State Council six months prior to the expiration of the license.

The administration of the Drug Manufacturing License operates under a two-tier regulatory framework. The NMPA, acting as the central competent authority under the state council, is responsible for formulating national policies, technical standards, and supervision guidelines for drug manufacturing. However, the specific authority empowered to grant, inspect, and renew the Drug Manufacturing License is the provincial drug regulatory department where the manufacturing enterprise is physically located. These provincial departments execute the acceptance inspections and issue the licenses in strict accordance with the standards and regulations established by the NMPA.

GMP

The good manufacturing practices (藥品生產質量管理規範) (“GMP”) was first promulgated on March 17, 1988 and subsequently revised on December 28, 1992 by the Ministry of Health. After the establishment of the NMPA, the GMP was amended on June 18, 1999 and became effective on August 1, 1999. As further amended by the Ministry of Health on January 17, 2011 and effective on March 1, 2011, the GMP stipulates the basic standards for pharmaceutical production which cover various areas including production plants and facilities, qualification of management personnel, documentation, material packaging and labeling, testing, production management, sales and return of products, and complaints of customers.

On August 2, 2011, the CFDA issued the Circular on Printing and Distributing the Administrative Measures for the Certification of Good Manufacturing Practice (關於印發藥品生產質量管理規範認證管理辦法的通知), which provided that newly established drug manufacturers, or existing drug manufacturers that wish to expand manufacturing scope or build new workshops shall apply for the GMP certification in accordance with the Implementing Rules for the Drug Administration Law. Those drug manufacturers that have already obtained the GMP certificates shall re-apply for the GMP certification within six months prior to the expiration date of the GMP certificates. On December 30, 2015, the CFDA issued the Notice on Effectively Implementing the

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Good Manufacturing Practice (關於切實做好實施藥品生產質量管理規範有關工作的通知), which provided that those drug manufacturers that failed to obtain the GMP certificates shall not be granted the drug manufacturing license.

On November 29, 2019, the NMPA issued the Announcement on Matters relating to the Implementation of the Drug Administration Law of the PRC (關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告), which confirmed that the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process is consistently in compliance with statutory requirements.

The Administrative Measures for Drug Inspection (Trial) (藥品檢查管理辦法(試行)) was issued by the NMPA on May 24, 2021 and revised on July 19, 2023, and the Administrative Measures for the Certification of Good Manufacturing Practice was repealed. The Administrative Measures for Drug Inspection (Trial) provides that onsite inspections shall be conducted pursuant to the GMP on a drug manufacturer applying for the Drug Manufacturing License for the first time, while for the drug manufacturers applying for the renewal of Drug Manufacturing License, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers' compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers' conformity to the GMP may be conducted where necessary.

Entrusted Manufacturing of Drugs

Pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs (藥品生產監督管理辦法) promulgated by the State Administration for Market Regulation on December 11, 2002 and last amended on January 22, 2020 and effective from July 1, 2020, the drug marketing authorization holders may entrust qualified drug manufacturing enterprises with drug production, provided that they shall evaluate the entrusted party's quality assurance capabilities and risk management capabilities. They shall also sign the quality agreement and the entrustment agreement with the entrusted party in accordance with the requirements of the guidelines for entrusted drug production promulgated by the NMPA and supervise the fulfillment of the obligations agreed by the entrusted party in the agreement; the entrusted party shall not recommission the production of the drugs it agreed to be entrusted to another third party. The drug marketing authorization holders shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the quality of medicines management. They shall regularly review the quality management system of the drug manufacturer and the drug distributor and supervise its continuous quality assurance and control capabilities.

Drug Operation License

According to the Drug Administration Law, the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (藥品經營和使用質量監督管理辦法), which was issued by the SAMR on September 27, 2023 and came into effect on January 1, 2024, whoever engages in the wholesale or retail of drugs shall be subject to the approval of the drug regulatory authority, obtain a Drug Operation License in accordance with the law. The drug marketing authorization holders may sell the drugs for which they have obtained drug registration certificate on their own or entrust a drug operating enterprise with the sale of such drugs. However, the drug marketing authorization holders engaged in retail activities of drugs shall obtain a Drug Operation License. Each Drug Operation License is valid for five years. Where it is necessary to continue the operation of drugs upon the expiration of the period of validity of the Drug Operation License, a drug operating enterprise shall file an application with the license-issuing organ for re-examination and issuance of license in 6 to 2 months before the expiration of the period of validity.

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OTHER RELEVANT REGULATIONS IN THE PRC PHARMACEUTICAL INDUSTRY

Coverage of the National Medical Insurance Program

The national medical insurance program was first adopted according to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (國務院關於建立城鎮職工基本醫療保險制度的決定) issued by the State Council on December 14, 1998. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (國務院關於開展城鎮居民基本醫療保險試點的指導意見), further enlarged the coverage of the basic medical insurance program, under which urban residents of the pilot district, rather than urban employees, may voluntarily join the Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (國務院關於整合城鄉居民基本醫療保險制度的意見) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

Pursuant to Interim Measures for the Administration of Drug Use in Basic Medical Insurance (基本醫療保險用藥管理暫行辦法) issued by the National Healthcare Security Administration on July 30, 2020, and became effective on September 1, 2020, the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue (基本醫療保險藥品目錄), the cost of drugs falls under which shall be paid by the Basic Medical Insurance Fund in accordance with regulations in the PRC. The pharmaceutical products listed in the PRC Medical Insurance Catalogue shall be chemical drugs, biological products, traditional Chinese drugs (including ethnic drugs) and Chinese medicine decoction pieces prepared according to national standards, all of which shall be clinically needed, safe and effective, and reasonably priced, with approval from the drug administration department in the PRC and obtainment of drug registration certificates. The administrative department of medical insurance under the State Council established and improved the dynamic adjustment mechanism so that the Medical Insurance Catalogue shall be adjusted once a year in principle. On the premise of meeting clinical needs, the medical insurance designated medical institutions are required to prioritize the preparation and utilization of drugs listed in the Medical Insurance Catalogue.

Pursuant to Interim Measures for the Administration of Drug Use in Basic Medical Insurance, expenses incurred by insured persons using drugs listed in the Medical Insurance Catalogue may be paid by the Basic Medical Insurance Fund with satisfaction of the following: (i) they are for the purpose of diagnosis or treatment of diseases; (ii) the diagnosis and treatment are in line with their conditions, the legal indications of the drugs, and the limited payment scope of the medical insurance; (iii) they are supplied by the designated medical institutions in compliance with the regulations, except for emergency and rescue medicines; (iv) the drug expenses paid by the unified fund shall be based on prescriptions from physicians or hospitalization instructions; and (v) they are examined by pharmacists or licensed pharmacists through the prescribed procedures. Western medicines and traditional Chinese drugs are divided into “Class A drugs” and “Class B drugs.” The use of “Class A drugs” is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of “Class B drugs” is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for “Class B drugs” is determined by the administrative department of medical insurance in provinces or regions subject to its overall planning.

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National Essential Drug List

According to the Circular on the Printing and Distribution of the Administrative Measures for the National Essential Drug List (關於印發國家基本藥物目錄管理辦法的通知) issued on February 13, 2015, the Opinions of the General Office of the State Council on Improving the National Essential Drugs System (國務院辦公廳關於完善國家基本藥物制度的意見) issued on September 13, 2018 and the National Essential Drug List (2018 version) (國家基本藥物目錄(2018年版)) (“**National Essential Drug List**”) issued by the NHC on September 30, 2018 and effective from November 1, 2018, basic healthcare institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the National Essential Drug List. The drugs listed in the National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by the National Development and Reform Commission (“**NDRC**”). Remedial drugs listed in the National Essential Drug List are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Drug Price Management

Pursuant to the Opinions on Promoting Drug Pricing Reform (推進藥品價格改革的意見), which was jointly promulgated by the authorities including the NDRC on May 4, 2015, from June 1, 2015, the original prices of the drugs formulated by the government will be canceled, except for narcotic drugs and Class I psychotropic drugs. The prices of narcotic drugs and Class I psychotropic drugs are still temporarily managed by the NDRC through the implementation of maximum factory prices and maximum retail prices. The drugs other than the narcotic drugs and Class I psychotropic drugs no longer adopted government-designated pricing.

Ethical Business Practices

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the approval for any of our drug candidates and begin commercializing our approved drugs in China in the future, our operations become subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法) and PRC Criminal Law (中華人民共和國刑法). Notably, since 2023, the National Health Commission (NHC), in conjunction with multiple other departments, has launched a year-long nationwide campaign to rectify corruption in the pharmaceutical sector. This initiative is supported by detailed regulatory rules such as the Guiding Opinions on Further Standardizing Medical Conduct and Promoting Rational Medical Examinations and the Nine Principles for Integrity in Practice for Medical Institution Staff. These specific regulations explicitly prohibit the disguised transfer of benefits under the guise of academic promotion, research collaboration, or consulting fees; strictly restrict pharmaceutical representatives from entering clinical areas without prior registration; and mandate the establishment of a “blacklist” system to penalize non-compliant enterprises and individuals. Furthermore, regulatory authorities have intensified penetrative audits regarding the authenticity of academic conferences and the flow of sponsorship funds, requiring companies to establish robust internal compliance controls to ensure the legitimacy and reasonableness of marketing expenditures. As advised by our PRC Legal Advisor, we have been in compliance with applicable anti-bribery, anti-corruption, and anti-kickback laws in all material respects during the Track Record Period and up to the Latest Practicable Date.

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OTHER SIGNIFICANT PRC REGULATIONS AFFECTING OUR BUSINESS ACTIVITIES IN THE PRC

Laws and Regulations relating to Company Law and Foreign Investment

The establishment, operation and management of enterprises in the PRC are governed by the Company Law of the PRC (中華人民共和國公司法) (“**Company Law**”), which was promulgated by the NPCSC on December 29, 1993 and became effective on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018, and December 29, 2023, respectively. Pursuant to the Company Law, companies are classified into two categories, namely limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail.

On March 15, 2019, the National People’s Congress (“**NPC**”) issued the Foreign Investment Law of the People’s Republic of China (中華人民共和國外商投資法) (“**Foreign Investment Law**”), which came into effect on January 1, 2020 and the Sino-Foreign Equity Joint Venture Enterprise Law of the People’s Republic of China (中華人民共和國中外合資經營企業法), the Wholly Foreign-Invested Enterprise Law of the People’s Republic of China (中華人民共和國外資企業法), and the Cooperative Joint Venture Enterprise Law of the People’s Republic of China (中華人民共和國合作經營企業法) were simultaneously abolished. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. According to the Foreign Investment Law and the Implementation Regulations for the Foreign Investment Law of the PRC (中華人民共和國外商投資法實施條例) issued by the State Council on December 26, 2019, with effect from January 1, 2020, “foreign investment” refers to the investment activities in the PRC carried out directly or indirectly by foreign individuals, enterprises or other organizations (“**Foreign Investors**”), including the following: (i) Foreign Investors establishing foreign-invested enterprises in the PRC alone or collectively with other investors; (ii) Foreign Investors obtaining shares, equities, shares of properties or other similar equities of Chinese domestic enterprises; (iii) Foreign Investors investing in new projects in the PRC alone or collectively with other investors; (iv) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The provisions of the Company Law, the Partnership Enterprise Law of the People’s Republic of China (中華人民共和國合夥企業法) and other laws shall apply to the form of organization of a foreign-invested enterprise, its organizational structure and the rules governing its activities.

Currently investment activities in the PRC by foreign investors are primarily governed by the (i) Special Administrative Measures for the Access of Foreign Investment (Negative List) (Edition 2024) (外商投資准入特別管理措施(負面清單)(2024年版)), which were promulgated by MOFCOM and the National Development and Reform Commission (“**NDRC**”) in September 2024 and came into effect since November 1, 2024, and (ii) Special Administrative Measures (Negative List) for the Access of Foreign Investment in Pilot Free Trade Zones (Edition 2021) (自由貿易試驗區外商投資准入特別管理措施(負面清單) (2021年版)) (collectively, “**Negative Lists**”), which were promulgated by MOFCOM and the NDRC in December 2021 and came into effect since January 1, 2022. The Negative Lists set out the special administrative measures in a unified manner in respect of the access of foreign investments, such as the industries that are prohibited for foreign investment, the limits on shareholding percentages of foreign investors and the requirements on the participation of foreign investors in the operation and management. The Negative Lists cover 11 industries, and any field not falling in the Negative Lists shall be administered under the principle of equal treatment for domestic and foreign investment. Our business as currently conducted does not fall within the confines of the Negative Lists and is not subject to foreign investment restrictions.

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The Measures for the Administration of Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (關於外國投資者併購境內企業的規定) is a core regulatory instrument governing cross-border M&A activities involving foreign investors in the PRC. Aligned with the upper-level legal framework of the Foreign Investment Law of the PRC, it clarifies that foreign investors conducting equity-based or asset-based mergers and acquisitions of domestic enterprises must adhere to the restrictions specified in the Negative List for Foreign Investment Access. Mergers and acquisitions involving key industries or posing potential impacts on national economic security are subject to special review procedures. Asset pricing in such transactions must be based on legally recognized valuation results to prohibit disguised capital transfer, and enterprises with foreign investment accounting for less than 25% are not entitled to preferential treatments applicable to foreign-invested enterprises. Foreign exchange registration, capital settlement, and other related matters arising from overseas investors’ mergers and acquisitions must comply with national foreign exchange administration regulations, and funds shall not be used for prohibited purposes. Additionally, if a merger or acquisition involves sensitive elements such as human genetic resources or important data, it must also comply with relevant regulatory requirements on biosecurity and cross-border data transfer security.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favorable than that accorded to domestic investors and their investments at the stage of investment access; while the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the PRC. The national treatment shall be granted to foreign investments outside of the negative list.

The Measures on Reporting Foreign Investment Information (外商投資信息報告辦法) was issued by MOFCOM and State Administration for Market Regulation on December 30, 2019 and came into effect on January 1, 2020, pursuant to which, for foreign investors carrying out investment activities directly or indirectly in the PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to such measures. When submitting an annual report, a foreign-invested enterprise shall submit the information such as basic enterprise information, the information on investor and actual controller thereof, enterprise business operation, assets and liability, as well as the relevant industry license information, if any special administrative measure for foreign investment access is involved.

Laws and Regulations on Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (境外投資管理辦法) issued by MOFCOM on March 16, 2009 and amended on September 6, 2014, and the Administrative Measures for the Outbound Investments of Enterprises (企業境外投資管理辦法) issued by the NDRC on December 26, 2017, and effective from March 1, 2018, if an enterprise in the PRC intends to make outbound investments, it shall be subject to approval or filing for the project, report relevant information, and cooperate in the supervisory inspections. Non-sensitive projects directly conducted by domestic enterprise in China, involving direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing.

Laws and Regulations relating to Foreign Exchange

The principal law governing foreign currency exchange in the PRC is the Foreign Exchange Administration Regulations of the PRC (中華人民共和國外匯管理條例) (“**Foreign Exchange Administration Regulations**”). The Foreign Exchange Administration Regulations were enacted by the State Council on January 29, 1996 and implemented on April 1, 1996. On January 14, 1997 and August 5, 2008, the State Council amended the Foreign Exchange Administration Regulations. According to the Foreign Exchange Administration Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign

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currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理總局) (“SAFE”) or its local counterpart and other relevant PRC governmental authorities.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (國家外匯管理局關於境外上市外匯管理有關問題的通知) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local Foreign Exchange Administration at the place of its establishment. The proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document or company securities offering documents, circulars of the shareholders, resolutions from the Board of Directors or at the shareholders’ meetings, and other disclosure documents.

According to the Circular of SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (國家外匯管理局關於改革和規範資本項目結匯管理政策的通知) (“SAFE Circular 16”) promulgated on June 9, 2016, and revised on December 4, 2023, by the SAFE, the Discretionary Foreign Exchange Settlement shall be unified for all the domestic institutions, while the use of foreign exchange incomes of capital projects by domestic institutions shall follow the principles of authenticity and self-use within the business scope of enterprises. The SAFE Circular 16 stipulates that the foreign exchange proceeds under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution may be used for expenditures under the current account within its business scope or the expenditures under the capital account permitted by the laws and regulations. The foreign exchange proceeds under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution (i) shall not be used directly or indirectly for expenditures beyond the business scope of the domestic institution or as prohibited by the laws and regulations; (ii) unless otherwise provided, shall not be used directly or indirectly for securities investments or other investments (except for wealth management products and structured deposits with risk rating not higher than level 2); (iii) shall not be used for offering loans to non-affiliated enterprises, unless expressly permitted by the business scope; (iv) shall not be used for the purchase of residential real estate not for self-use (except for enterprises engaged in real estate development and real estate leasing).

According to the Circular of SAFE on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (國家外匯管理局關於優化外匯管理支持涉外業務發展的通知) promulgated by the SAFE on April 10, 2020, the reform of facilitating the payments of incomes under the capital projects shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, including capital funds, foreign debt and overseas listing, for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

Distribution of Dividends

Pursuant to the provisions of the Company Law, when distributing each year’s profits after taxation, the company shall set aside 10% of its profits for the company’s statutory common reserve fund until the fund has reached more than 50% of the company’s registered capital. When the company’s statutory common reserve fund is not sufficient to make up for the company’s losses for the previous years, the current year’s profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon the

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resolution at a shareholders’ general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its common reserve fund, the remaining profits after taxation shall be distributed to the shareholders.

On January 26, 2017, the SAFE issued the Notice on Promoting the Reform of Foreign Exchange Administration and Improving the Review of Authenticity and Compliance (關於進一步推進外匯管理改革完善真實合規性審核的通知) which provided that when processing the outward remittance of profits of a domestic institution equivalent to more than 50,000 US dollars, the bank shall, in light of the principle of genuine transaction, review the profit distribution resolution made by the board of directors (or by the partners), original tax filing form and audited financial statements relating to the outward remittance of profits, and chop on the original tax filing form to endorse the amount and date of the outward remittance. The domestic institution shall make up for its losses during the previous years according to the laws before remitting the profits.

Laws and Regulations Related to Intellectual Property Rights

Patents

Pursuant to the Patent Law of the PRC (中華人民共和國專利法) (“**Patent Law**”) promulgated by the NPCSC on March 12, 1984, and amended on September 4, 1992, August 25, 2000 December 27, 2008, and October 17, 2020, respectively, with the latest amendments effective from June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (中華人民共和國專利法實施細則) promulgated by the State Council on June 15, 2001, with the latest amendments on December 11, 2023, effective from January 20, 2024, the patents in the PRC refer to invention, utility model and design. An invention or a utility model to be granted as a patent shall have novelty, inventiveness and practicality. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining, and approving patent applications. A patent is valid for a twenty-year term for an invention, a ten-year term for a utility model, or a fifteen-year term for a design, commencing from their respective application dates.

The term of an invention patent related to a new drug may be extended. According to the provisions of the Patent Law and the Implementation Rules of the Patent Law of the PRC, for the purpose of compensating for the time taken to examine and approve a new drug to be marketed, the patent administrative department under the State Council shall grant compensation to the validity period of patent rights for the invention patents of new drugs approved to be marketed in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights after a new drug is approved to be marketed shall not exceed 14 years. Applications for patent term extension must be filed within six months after the drug is marketed, and requires the submission of supporting documentation regarding clinical trials and the approval timeline. During the validity compensation period of patent rights, the scope of protection of the invention patent of a new drug is limited to the new drug and its approved indications-related technical solutions; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as those before the validity compensation period.

On July 4, 2021, the NMPA and the National Intellectual Property Administration jointly issued the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) (藥品專利糾紛早期解決機制實施辦法(試行)), which establishes an early resolution mechanism of pharmaceutical patent disputes; the pharmaceutical marketing authorization holder shall, within 30 days upon obtainment of pharmaceutical registration certificates, register the relevant pharmaceutical patent information on the PRC Marketing Pharmaceutical Product Patent Information Registration Platform (中國上市藥品專利信息登記平台). When an application is submitted by a chemical generic drug applicant for its marketing permit, he/she shall make declaration of each relevant pharmaceutical patent of the generic drugs in accordance with the disclosed patent information on the PRC Marketing Pharmaceutical Product Patent Information Registration Platform. Provided there are disputes from

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the patentee or interested party considering the patent declaration, he/she may, within 45 days from the disclosure date of the drug marketing authorization application by drug evaluation institutions in the PRC, initiate legal proceedings in the People's Court or apply for an administrative ruling to the patent administration department of the State Council on whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent right.

As advised by our PRC Legal Advisor and our legal advisors as to PRC intellectual property laws, as of the Latest Practicable Date, our patent applications and maintenance have been in compliance with the requirements of the Patent Law and its Implementing Regulations, and there are no disputes related to patent terms.

Trademark

Pursuant to the Trademark Law of the PRC (中華人民共和國商標法) promulgated by the NPCSC on August 23, 1982, and amended on February 22, 1993, October 27, 2001 and August 30, 2013 respectively, and last amended on April 23, 2019 with the latest amendment effective on November 1, 2019 and the Implementation Regulations of the Trademark Law of the PRC (中華人民共和國商標法實施條例) promulgated by the State Council on August 3, 2002 which became effective on September 15, 2002 and was revised on April 29, 2014 and the latest amendment became effective on May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within 12 months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled.

Copyright

Copyright is protected by the Copyright Law of the PRC (中華人民共和國著作權法) promulgated by the NPCSC on September 7, 1990 and last amended on November 11, 2020 with the latest amendment effective on June 1, 2021 and the Implementation Regulations of the Copyright Law of PRC (中華人民共和國著作權法實施條例) issued by the State Council on August 2, 2002 and last amended on January 30, 2013 with the latest amendment effective on March 1, 2013, which provided provisions on the classification of works and the obtaining and protection of copyright and the related rights.

Domain Names

Domain names are protected by the Administrative Measures of Internet Domain Names (互聯網域名管理辦法) issued by the Ministry of Industry and Information Technology ("MIIT") on August 24, 2017 and effective from November 1, 2017 and the Implementing Rules on Registration of China Country Code Top-level Domain Names (國家頂級域名註冊實施細則) issued by China Internet Network Information Center on June 18, 2019. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. The China Internet Network Information Center is responsible for the administration of registration of China country code top-level domain names. Domain name registrations are processed by the domain name registration service agencies established pursuant to the relevant provisions. The applicants become domain name holders upon successful registration.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (中華人民共和國反不正當競爭法) promulgated by the NPCSC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019 respectively and the Provisions of the Supreme People's Court on Several Issues Concerning

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the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement (最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定) issued by the Supreme People’s Court on September 10, 2020 and effective from September 12, 2020, the term “trade secrets” refers to technical, operational and other business information that is unknown to the public, has business value, may create business interests or profits for its legal owners or holders, and is maintained as a secret with relevant security measures taken by its right holders. According to the Anti-Unfair Competition Law of the PRC, business operators are prohibited from infringing others’ trade secrets by (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph; (iii) disclosing, using or allowing other person to use a trade secret in its possession in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting, tempting or aiding a person into or in acquiring, disclosing, using or allowing other person to use the trade secret of the right holder in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known the above mentioned illegal conducts but nevertheless acquires, uses or allows other persons to use such trade secrets, the third party shall be deemed to have infringed others’ trade secrets. The right holders whose trade secrets are infringed may apply for administrative corrections, and the regulatory authorities shall order to stop any illegal activities and impose fine penalties on the infringers.

Regulations relating to Enterprise Income Tax and Value-added Tax

EIT

Pursuant to the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法) (“**EIT Law**”) promulgated by the NPCSC on March 16, 2007, which became effective from January 1, 2008, and last amended on December 29, 2018, enterprises shall be classified into resident enterprises and non-resident enterprises. The income tax rate of resident enterprises is 25%, while the income tax rate of non-resident enterprises is 20%. According to the EIT Law and the Implementation Regulations for the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法實施條例) (“**Implementation Regulations for EIT Law**”) issued by the State Council on December 6, 2007, which became effective from January 1, 2008, and last amended on April 23, 2019, enterprise income tax shall be payable by a resident enterprise for the income derived from or accruing in or outside the PRC. Enterprise income tax shall be payable by a non-resident enterprise with office or premises within the territory of the PRC for the income derived from or accruing in the PRC by its office or premises, and the income derived from or accruing outside the PRC for which its office or premises has a de facto relationship. Where the non-resident enterprise has no office or premises within the territory of the PRC or the income derived or accrued has no de facto relationship with its office or premises, enterprise income tax shall be payable by the non-resident enterprise for the income derived from or accruing in the PRC at a reduced rate of 10%.

According to the Arrangement between Chinese Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排) (“**Double Tax Avoidance Arrangement**”), the withholding tax rate in respect of the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise and certain other conditions are met, including: (i) the Hong Kong enterprise must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) the Hong Kong enterprise must have directly owned such required percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (關於執行稅收協定股息條款有關問題的通知) issued on February 20, 2009 by the STA, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such

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reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties (關於稅收協定中“受益所有人”有關問題的公告) issued by the STA on February 3, 2018 and effective from April 1, 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the abovementioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

VAT

According to Value-Added Tax Law of the People’s Republic of China and the Regulation on the Implementation of the Value-Added Tax Law of the People’s Republic of China, which effective on January 1, 2026, entities and individuals selling goods or processing, repair and fitting-out services, selling services, intangible assets, immovable property and importing goods within the territory of the PRC shall be subject to VAT. The applicable VAT rates, depending on the nature of the taxable acts of the general taxpayer, are 13%, 9%, 6%, 3% and 0%.

Laws and Regulations Relating to Product Quality

The Product Quality Law of the PRC (中華人民共和國產品質量法) promulgated on February 22, 1993 by the NPCSC and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively, is the main law regulating the supervision and management of quality of products in China. According to the Product Quality Law of the PRC, producers shall be responsible for the quality of the products they produce, and sellers shall take measures to maintain the quality of the products they sell. If a defect in a product causes physical injury or damage to property other than the defective product, the producer shall bear the liability for compensation, unless the producer can prove any of the following circumstances: (i) the product has not been put into circulation; (ii) the defect causing the damage did not exist when the product was put into circulation; (iii) when the product was put into circulation, the level of science and technology at the time was not sufficient to detect the existence of the defect.

Pursuant to the Civil Code of the PRC (中華人民共和國民法典) promulgated by the NPC on May 28, 2020 and coming into effective on January 1, 2021, where a patient suffers damage due to defects in drugs, he/she may seek compensation from the drug marketing authorization holder, producer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder or the producer.

Laws and Regulations Relating to Safety Production

Pursuant to the Safety Production Law of the PRC (中華人民共和國安全生產法) promulgated by the NPCSC on June 29, 2002 and amended on August 31, 2014 and June 10, 2021 respectively with the latest amendment taking effect on September 1, 2021, production and operation units shall abide by the Safety Production Law of the PRC and other laws and regulations related to production safety, strengthen production safety management, and establish a sound production safety responsibility system and formulate a set of production safety rules and regulations for all employees; increase the efforts to guarantee the input of funds, supplies, technology and personnel to production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; construct a “dual-prevention” mechanism consisting of graded management and control of safety risks and examination and control of potential risks, improve the risk prevention and resolution mechanism, enhance production safety levels and ensure production safety.

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Precursor Chemicals

Pursuant to the Regulation on the Administration of Precursor Chemicals (易製毒化學品管理條例) promulgated by the State Council on August 26, 2005, which became effective on November 1, 2005 and was amended on July 29, 2014, February 6, 2016 and September 18, 2018 respectively, the State regulates the production, operation, purchase, transport, import and export of precursor chemicals. Unit intending to purchase Category II and III precursor chemicals shall file with the public security authorities of the local people’s government at the county level for the types and quantities of precursor chemicals required before making the purchase.

Labor, Social Insurance and Housing Fund

The Labor Law of the PRC (中華人民共和國勞動法) promulgated by the NPCSC on July 5, 1994 and last amended on December 29, 2018 and the Labor Contract Law of the PRC (中華人民共和國勞動合同法) promulgated on June 29, 2007, effective from January 1, 2008, and last amended on December 28, 2012 and effective on July 1, 2013 stipulate the relationship between the employers and the employees, and specifies the terms and conditions of the labor contracts.

Pursuant to the Social Insurance Law of the PRC (中華人民共和國社會保險法) promulgated by the NPCSC on October 28, 2010, effective from July 1, 2011, and last amended on December 29, 2018, the Provisional Regulations for the Collection and Payment of Social Insurance Premiums (社會保險費徵繳暫行條例) issued by the State Council on January 22, 1999 and last amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (住房公積金管理條例) issued by the State Council on April 3, 1994, and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to pay social insurance premiums such as basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance for their employees, and contribute to housing provident funds. According to the Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), which became effective on September 1, 2025, where the employer fails to make social insurance contributions in accordance with the law, and the employee requests to terminate the labor contract and claim economic compensation in accordance with item (3) of Article 38 of the Labor Contract Law of the People’s Republic of China (中華人民共和國勞動合同法), the people’s court shall uphold such claim.

The Interpretation primarily applies to circumstances in which an employer fails to make statutory social insurance contributions. We make contributions to social insurance and housing provident funds in accordance with applicable PRC laws and regulations. During the Track Record Period and up to the Latest Practicable Date, no employees had filed any claims, litigation, arbitration, or complaints against the Group regarding social insurance and housing provident fund payments. Furthermore, no penalties or rectification orders had been issued against the Group by the relevant PRC regulatory authorities. As such, as confirmed by our PRC Legal Advisor, based on its review of our Group’s social insurance and housing provident fund compliance documentation for the Track Record Period and up to the Latest Practicable Date, no material non-compliance or disputes in relation to such contributions have been identified, and the foregoing judicial interpretation is not expected to have a material adverse impact on our Group.

Regulations Relating to Cybersecurity and Data Exploration Security

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with 12 other governmental authorities, promulgated the Measures for Cybersecurity Review (網路安全審查辦法) (“Measures for Cybersecurity Review”), which became effective on February 15, 2022 and provides that critical information infrastructure operators that purchase network products and services and data processing operators engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review.

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On July 7, 2022, the CAC issued the Measures on the Security Assessment of Cross-border Data Transfer (數據出境安全評估辦法) (“**Security Assessment Measures**”), which took effect on September 1, 2022. The Security Assessment Measures generally apply to data processors that provide abroad important data or personal information that was collected or produced through operations within the PRC. Companies that are subject to the Security Assessment Measures need to conduct data mapping on cross-border data transfers, prepare the self-assessment and submission, as well as implement data classification and apply controls on cross-border data transfers.

In March 2024, the CAC issued the Provisions on Promoting and Regulating Cross-border Data Flows (促進和規範數據跨境流動規定), which required security assessment for the following types of cross-border data transfers (i) for critical information infrastructure operators, the outbound transfer of personal information or important data, and (ii) for data processors that are not critical information infrastructure operators, the outbound transfer of important data or the cumulative outbound transfer within one calendar year of the personal information of over one million people or the sensitive personal information of over 10,000 people. These provisions also stipulated that, when data processors that are not critical information infrastructure operators engage in the cumulative outbound transfer within one calendar year of the personal information of over 100,000 people but less than one million people or the sensitive personal information of less than 10,000 people, the data processors must enter into a standard contract for cross-border transfer of personal information with the data recipient or obtain a certification for the protection of personal information. Furthermore, these provisions clarified that data processors do not need to treat any data as “important data” the outbound transfer of which requires security assessments, if government authorities have not declared or notified them that the data are “important data”.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (科學數據管理辦法) (“**Scientific Data Measures**”). The regulations establish a comprehensive definition of scientific data and set forth relevant management rules. According to the Scientific Data Measures, the provision of scientific data involving state secrets in the context of external exchanges and cooperation requires approval from the competent government authorities in accordance with confidentiality management procedures. Furthermore, when scientific data generated through funding from Chinese government budgets is used to write papers for publication in foreign academic journals, and such data needs to be submitted externally, the authors must submit the scientific data to their affiliated institutions for unified management prior to publication. The data collected or generated in connection with our services currently and historically do not fall within the definition of “state secrets.” Accordingly, our PRC subsidiaries have not been required to, and have not since their establishment, sought governmental approval. Our PRC Legal Advisor is of the view that, based on the foregoing facts, our operations do not involve any “state secrets” as defined under applicable PRC laws, and no PRC subsidiary has been engaged by any client to undertake any project involving “state secrets.” Therefore, our PRC subsidiaries are not required to obtain governmental approval in accordance with confidentiality management procedures.

Regulations Relating to Overseas Listing

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (境內企業境外發行證券和上市管理試行辦法) (“**Trial Administrative Measures**”) released by the CSRC on February 17, 2023 and come into effect on March 31, 2023, domestic enterprise in the PRC that issues securities outside the PRC shall file with the CSRC in accordance with the Trial Administrative Measures. For the overseas initial public offering or listing, issuers shall file with the CSRC within three working days after the submission of its application for listing in overseas region.

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Confidentiality and Archives Administration Concerning Overseas Listing

Pursuant to the Provisions on Strengthening Confidentiality and Archives Administration Concerning Overseas Securities Offerings and Listings by Domestic Enterprises (關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定), which was jointly announced by numerous departments including CSRC on February 24, 2023 and came into effect since March 31, 2023, during the overseas issuance and listing activities of domestic enterprises, such enterprises and securities companies, securities service institutions which provide corresponding services shall strictly comply with the relevant laws and regulations of PRC and the requirements of these Provisions, in order to strengthen the legal awareness on safeguarding national secret and strengthening archives administration, establish a sound system on confidentiality and archives administration, and adopt necessary measures for fulfilling its obligations on confidentiality and archives administration, They shall not leak any national secrets and work secrets of national authorities, and shall not jeopardize the national and public interests. A domestic enterprise, which provides or publicly discloses documents and information about the national secrets and the work secrets of national authorities to entities or individuals such as securities companies, securities service institutions and overseas regulatory authorities, or provides such documents and information through its overseas listed entity, shall report to, and obtain approval from competent authority with approval authorizations in accordance with law, and shall report to the administrative department of confidentiality at the same level for filing. A domestic company that provides or publicly discloses documents and information that may pose adverse effects to national security or public interests to relevant entities or individuals including securities companies, securities service institutions, and overseas regulators, or provides or publicly discloses such documents and information through its overseas listed entity, shall strictly fulfill relevant procedures stipulated by applicable national regulations.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“**FDCA**”) and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (“**PHSA**”) and their respective implementing regulations. Both drugs and biologics also are subject to other federal, state, and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals to manufacture or market drugs and biologics in the United States and the subsequent compliance with appropriate federal, state, local, and non-U.S. applicable statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative proceedings, civil actions, government prosecution, judicial sanctions or any combination of them in the United States. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any administrative proceeding on action or any judicial enforcement action could have a material adverse effect on our business, financial condition and results of operations as well as the market’s acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other statutory and regulatory systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply could also subject us to administrative actions, government prosecution or judicial sanctions (or any combination of them).

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Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA’s GLP regulations. A sponsor of an investigational new drug application (“**IND**”) must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. The FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as www.clinicaltrials.gov.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice (“**GCP**”) and human subject protection regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“**IRB**”), often under the auspices of a university and sometimes a private, independent organization, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted the FDA for review and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

Clinical trials generally are conducted in three sequential phases, known as phase 1, phase 2 and phase 3, and may overlap.

- phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

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Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with FDA’s current good manufacturing practices (“cGMP”).

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a NDA. Unless deferred or waived, NDAs, or supplements, must contain data adequate to assess the safety and efficacy of the product at the proposed commercial dosing regimen and administration for the claimed indications in all relevant populations, including any pediatric subpopulations. The submission of an NDA is subject to the payment of a user fee and an annual prescription drug product program fee to the FDA although in certain circumstances the FDA may waive the annual prescription drug product program fee if the drug qualifies for orphan drug designation.

Within 60 days of its receipt, the FDA reviews the NDA to ensure that it is sufficiently complete for substantive review before it accepts the NDA for filing. After accepting the NDA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product’s manufacturing is cGMP-compliant to assure the product’s identity, strength, quality and purity. Before approving the NDA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee, generally consisting of a panel of experts, to review whether the application should be approved and under what conditions, and the FDA typically considers such recommendations when making decisions.

The FDA may refuse to approve the NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may withdraw the application and resubmit the NDA when all the data addressing all of the deficiencies identified in the letter is available, or the applicant may request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase 4 clinical trials, to further assess a product’s safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

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Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review of, drugs to treat serious conditions and fill an unmet medical need. Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. The FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition. Determining whether a disease is serious is a matter of judgment, but generally the FDA considers whether the proposed drug will affect factors such as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. To address an unmet medical need, the proposed drug may be developed as a treatment or preventative measure for a disease that does not have a current therapy. The type of information necessary to demonstrate unmet medical need varies with the stage of drug development: early in development, nonclinical data, mechanistic rationale, or pharmacologic data will suffice; later in development, clinical data should be utilized.

A sponsor may request Fast Track designation when the sponsor files a BLA application or any time thereafter prior to the receipt of marketing approval. If a new drug product meets the requisite criteria for Fast Track designation, the FDA should grant the application. However, the FDA may rescind Fast Track designation, if the FDA determines the criteria for Fast Track designation are no longer met. The FDA will notify the sponsor in writing of its intent to rescind the designation through a “Intent to Rescind Fast Track Designation” letter, which will include the criteria for making the determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing designation and request a meeting to discuss the designation for the product. The rescinding of a Fast Track designation does not necessarily mean the product is not promising or that the product may not receive marketing approval. It means that the criteria for Fast Track designation are no longer met. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all of the benefits of Fast Track designation, which include more frequent meetings and written communication with the FDA, rolling review, and eligibility for Accelerated Approval and priority review.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (“PDUFA”) guidelines. These six and ten-month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

Accelerated Approval

Under the FDA’s accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct

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required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough Designation

Another program potentially available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and according to FAQs published by the FDA (current as of February 3, 2022), the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the products marketing application, including by meeting with the sponsor throughout the products development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances. The impacts on the clinical development and registration of drugs receiving Orphan Drug designation are: the sponsors may be provided with (1) a tax credit of 50 percent of the cost of conducting human clinical trials, (2) federal research grants for clinical testing of new therapies to treat and/or diagnose rare diseases; (3) eligibility for seven-year marketing exclusivity and (4) a waiver of NDA PDUFA fees. The approval of an orphan drug designation request does not alter the standard regulatory requirements and processes for obtaining marketing approval. Sponsors must establish safety and efficacy of a compound to treat a rare disease through adequate and well-controlled studies.

The FDA may revoke orphan-drug designation for any drug if the agency finds that (i) the request for designation contained an untrue statement of material fact; (ii) the request for designation omitted required or material information; or (iii) the FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request. For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor's exclusive marketing rights for the drug but not the approval of the drug's marketing application.

Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

If the FDA revokes an orphan-drug designation, it will publicize that the drug is no longer designated in accordance with 21 CFR 316.28. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all the benefits of Orphan Drug designation.

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Post-Marketing Requirements

Following approval of a new product, the manufacturer of the approved product is subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events (“**AEs**”) experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies such as the Department of Justice actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities as well as potential tort liability. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (“**REMS**”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities according to approved manufacturing processes and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufacturers, therefore the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall, any of which could have a material adverse effect on our business, financial condition and results of operations.

Once an approval is granted, if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market, the FDA may take enforcement actions such as issuing Warning Letters or Untitled Letters, ordering removal of the product from the market until deficiencies are remedied, withdrawing the approval of the product, or imposing civil and criminal penalties. Corrective action in response to these enforcement activities could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in

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revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences which could arise from such regulatory violations include, among other things: (i) restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls; (ii) fines, warning letters or holds on post-approval clinical trials; (iii) refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals; drug seizure or detention, or refusal to permit the import or export of drugs; and (iv) injunctions or the imposition of civil or criminal penalties.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, “ACA”), became law in the United States in March 2010, and has driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare is financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on the pharmaceutical companies’ share of sales to federal health care programs.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, U.S. President Donald J. Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. There may be other efforts to challenge, repeal or replace the ACA.

BIOSECURE Act

On December 18, 2025, the U.S. legislation titled the BIOSECURE Act (the “BIOSECURE Act”) was signed by President Trump. The enacted BIOSECURE Act prohibits federal agencies from contracting with or funding companies that are designated “biotechnology companies of concern.” The BIOSECURE Act’s final definition of “biotechnology companies of concern” includes (A) entities on the Department of Defense’s section 1260H list of Chinese military companies operating in the United States (known as the “1260H List”), and (B) entities that will be named through a process headed by the Office of Management and Budget (“OMB”), who must supplement the list of biotechnology companies of concern within one year of enactment. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized.

The OMB must publish the initial list of “biotechnology companies of concern” within one year of the FY2026 NDAA’s enactment (i.e., by December 2026). Within 180 days of publishing this list, OMB must issue implementation guidance for the BIOSECURE Act’s requirements. The Federal Acquisition Regulation (“FAR”) Council must then update the FAR within one year. Prohibitions for 1260H List entities take effect 60 days after the FAR revision, while prohibitions for companies newly named by the OMB take effect 90 days after the FAR revision. A

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grandfathering period applies for up to five years after the FAR revision, where the prohibitions do not apply to biotechnology equipment or services produced or provided under contracts or agreements (including previously negotiated contract options) entered into before the applicable effective date.

We are of the view that the BIOSECURE Act would not have a material and adverse impact on our business, primarily because we, or any of our subsidiaries, are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future. Furthermore, to the best of our knowledge, none of our business partners are using any services provided by us under the respective arrangements in connection with any federal contracts, loans, grants or funding. During the Track Record Period and up to the Latest Practicable Date, we did not have business relationship with any entity included in the 1260H List.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of NDA/BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of the FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.