We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business and operations.

REGULATIONS RELATING TO DRUGS IN CHINA

Drug Administration Laws and Regulations

The PRC Drug Administration Law (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") on September 20, 1984, and last amended on August 26, 2019, and the Implementing Measures of the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) (the "**Drug Administration Law Implementing Measures**") issued by the State Council on August 4, 2002, and last amended on December 6, 2024 have together laid down the legal framework for the administration of drugs, including the research, development, manufacturing and business operation of new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises, and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of drugs. The primary regulation governing clinical trial applications, marketing authorization, and post-approval amendment and re-registration is known as the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Administrative Measures for Drug Registration**"), promulgated by the China Food and Drug Administration (the "**CFDA**") on February 28, 2005, and last revised on January 22, 2020, by the State Administration for Market Regulation of the PRC (the "**SAMR**"), and became effective on July 1, 2020.

Non-Clinical Research and Animal Testing

The SAMR requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration, non-clinical drug safety studies shall comply with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the "**GLP**"). The GLP was issued by the CFDA on August 6, 2003 and latest revised on July 27, 2017 to improve the quality of non-clinical research, and the good laboratory practice has been implemented since September 1, 2017. Pursuant to the Measures for Administration of Certification of the Good Laboratory Practice for Nonclinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) promulgated by the National Medical Products Administration ("**NMPA**") on January 19, 2023, the NMPA is responsible for the certification of non-clinical research institutions nationwide, while the local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking non-clinical pharmaceutical research by evaluating such institution's organizational administration, research personnel, equipment and facilities, and the operation and administration of non-clinical pharmaceutical projects. A GLP Certificate will be issued by the NMPA if all the relevant requirements are satisfied.

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, 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 activities regulated under relevant laws and regulations.

Approval and Reform for Clinical Trials of New Drugs

Pursuant to the Drug Administration Law, the Drug Administration Law Implementing Measures and the Administrative Measures for Drug Registration, new drug registration applications are subject to clinical trials. The Center for Drug Evaluation (the "**CDE**"), an institution under the NMPA, is responsible for the applications for clinical trials of new drugs.

The NMPA has taken certain measures to improve the efficiency for approving clinical trial applications, and enhanced the extent of supervising and implementation of the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the "**PRC GCP**"), to ensure the completeness of the data. The PRC GCP was issued by the CFDA on August 6, 2003 and was latest revised by the NMPA and the National Health Commission ("**NHC**"), which took effect from July 1, 2020.

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, established a reform framework of the evaluation and approval system for drugs and medical devices, and indicated 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 of the CFDA on Several Policies on the Evaluation and Approval of Drug Registration (《國家食品藥品監督管理總局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, further simplified the approval process of drugs that the IND of new drugs are subject to one-off umbrella approval instead of declaration, evaluation and approval by stages.

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.

According to the Announcement of the NMPA on Adjusting the Evaluation and Approval Procedures for Clinical Trials of Drugs (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》) issued by the NMPA on July 24, 2018, which took effect therefrom, within 60 days from the acceptance of the IND and relevant fees paid up, if the applicant has not received any negative or questioning opinion from the CDE, the applicant may conduct the clinical trials for drugs pursuant to the protocol submitted.

The Priority Evaluation and Approval Procedures for Marketing Approvals of Drugs (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) issued by the NMPA on July 7, 2020, further indicated that a fast track IND or drug registration pathway will be available to the innovative drugs.

Clinical Trial Registration of Drugs

According to the Administrative Measures for Drug Registration, upon obtaining the approval of IND, the applicant shall, prior to conducting the clinical trials of the drugs, register the information in relation to the clinical trial protocol on the registration and information publication platform for clinical trials of drugs.

Pursuant to the Announcement on the 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, for all the clinical trials approved by the CFDA and conducted in the PRC, the applicants shall log in the registration and information publication platform for clinical trials of drugs to register, and publish the information

of, the clinical trials. The applicant shall complete the pre-registration of the trials within one month after obtaining the approval for the IND, so as to obtain the unique registration number for the trial, and complete the registration of follow-up information before the enrollment of the first subject. If the applicant fails to complete the first submission and publication within one year after obtaining the approval for the IND, the applicant shall submit an explanation; if the applicant fails to complete the first submission and publication within three years after obtaining the approval for the IND, the approval for the IND will expire automatically.

Phases of Clinical Trials and Communication with the CDE

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 I, II, III and IV clinical trials, as well as the bioequivalence trials, which include clinical pharmacological 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.

According to the Announcement of the NMPA on Adjusting the Evaluation and Approval Procedures for Clinical Trials of Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the clinical trials of a new drug has been approved, upon the completion of Phase I and II clinical trials and prior to Phase III clinical trials, the applicant shall apply to the CDE for a communication session, to discuss with the CDE the key technical issues including the design of Phase III clinical trials.

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 December 10, 2020 and effective therefrom, during the research and development, and application for registration stages of innovative drugs, the applicants may propose communication sessions with the CDE. The forms of communication can be face-to-face conference, video conference, telephone conference or written reply. The communication sessions are classified into three types. Type I sessions are held to address the key safety issues in the clinical trials of drugs and the key technical issues in the research and development 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 II clinical trials and prior to commencement of Phase III 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.

Filings for Gathering and Collecting Human Genetic Resources

To effectively protect and rationally utilize the human genetic resources in the PRC, the Ministry of Science and Technology and the Ministry of Health (the "**MOH**") jointly issued the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》) on June 10, 1998, which was replaced by Administrative Regulations of the PRC on Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council on May 28, 2019 and amended on March 10, 2024. According to the Service Guidance for the Administrative Licensing Items of Collection, Gathering, Trading, Export or Exit 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》) issued by the Ministry of Science and Technology on July 2, 2015 and effective therefrom, and the Notice on Implementing the Administrative Licensing for Collection, Gathering, Trading, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) issued by the Ministry of Science and Technology on August 24, 2015 and effective therefrom, the collection, gathering or research activities of human genetic resources participated by a foreign-invested sponsor falls within the scope of international cooperation, and the cooperating PRC organization shall apply for the approval of the China Human Genetic Resources

Management Office via the online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Procedures for 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》), which became effective on December 1, 2017, simplifying the procedures for the examination and approval for collection and gathering of human genetic resources for marketing a drug in the PRC.

Pursuant to the Administrative Regulations on Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council on May 28, 2019 and revised on March 10, 2024 which became effective on May 1, 2024, in order to obtain marketing approvals for the relevant drugs and medical devices in the PRC, no approval is required in the event international cooperating clinical trials are conducted at clinical institutions using the human genetic resources of the PRC but not involving the exit of human genetic resource materials. However, the cooperating parties shall file with the competent health department of the State Council the type, quantity and purpose of the human genetic resources intended to be used prior to conducting clinical trials.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") which was later amended on April 26, 2024 and effective since then, 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; (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent health department of 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, shall be approved by the competent health department of the State Council.

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》) (the "**Human Genetic Resources Implementing Rules**"), which became effective on July 1, 2023, further clarifying the requirements for administrative licensing, record -filing and security review in respect of the collection, preservation, use, and outbound supply of Chinese human genetic resources, and detail the issues concerning relevant supervision, inspection and administrative penalties.

New Drug Application, Approval and Registration

According to the Administrative Measures for Drug Registration, upon completion of pharmacological and toxicological studies, clinical trials and other research supporting the marketing registration of drugs, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply for the New Drug Approval (the "**NDA**"). The NMPA shall evaluate the application pursuant to applicable laws and regulations. The applicant must obtain the NDA before the drugs can be manufactured and sold in the PRC. If (i) a drug is used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials of the drug can prove the efficacy and forecast the clinical value of the drug; (ii) a drug which is urgently needed for public health and the data of clinical trials of the drug can show the efficacy and forecast the clinical value of the drug; or (iii) a vaccine which is urgently

needed to deal with major public health emergencies or deemed to be urgently needed by the NHC, and by assessment the benefit of the vaccine outweighs the risk, the applicant may apply for the conditional NDA during the clinical trials of the drug or vaccine.

According to the Administrative Provisions on Special Examination and Approval of New Drug Registration (《新藥註冊特殊審批管理規定》) issued by the CFDA on January 7, 2009 and effective therefrom, the special examination and approval by the CFDA for new drug registration applications applies when (i) the effective constituent extracted from, among others, plants, animals or minerals or the preparations thereof have never been marketed in the PRC, or the medicinal materials are newly discovered or the preparations thereof; (ii) the chemical raw medicines or the preparations thereof, or the biological products have not been approved for marketing either in the PRC or aboard; (iii) the new drugs are for the treatment of such diseases as AIDS, malignant tumors or rare diseases with distinctive clinical treatment advantages; or (iv) the new drugs are for the treatment of the diseases currently lacking effective treatment. Under the circumstances of (i) or (ii), the drug registration applicant (the "**Applicant**") may apply for the special examination and approval when submitting the application for clinical trials of the new drug; while, under the circumstances of (iii) or (iv), the Applicant may only apply for the special examination and approval when applying for production. The CFDA shall, based on the application of the Applicant, give priority to those registration applications which are determined in compliance with the aforementioned conditions after examination during the registration process, and enhance the communication with the Applicant.

On November 11, 2015, the CFDA issued the Circular on Several Policies of the Review and Approval of Drug Registrations (《關於藥品註冊審評審批若干政策的公告》), which provided fast-track clinical trial approvals and drug registration pathways for the following new drug applications: (i) registration of innovative drugs for the prevention or treatment of HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of geriatric drugs for the treatment of 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 the clinical trials of new drugs which have been already approved in the United States or the European Union, or concurrent drug registration applications for drugs which are in the process of applying for marketing approvals and have passed onsite inspections by the competent review and approval authorities of drugs of the United States or the European Union, and are manufactured with the same production line in the PRC; and (viii) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and applications for manufacturing approvals of drugs with urgent clinical need and patent expiry within one year.

In addition, on May 17, 2018, the NMPA and the NHC jointly issued the Circular on Issues Concerning Optimizing the Review and Approval of Drug Registrations (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the drug review and approval process.

On July 7, 2020, the NMPA issued the Working Procedures for Priority Review and Approval of Drug Marketing Approvals (Trial) (《藥品上市許可優先審評審批工作程序(試行)》), which provided that during the clinical trials of drugs, for innovative drugs or improved new drugs for the prevention or treatment of severe life-threatening or life-quality-affecting diseases currently lacking effective prevention or treatment method or having obvious clinical advantages compared to the existing treatment method shown by sufficient evidence, the applicant may apply for the application of the procedures for breakthrough therapeutics during Phase I or II clinical trials, and usually no later than the Phase III clinical trials.

Drug Manufacturing License

Pursuant to the Drug Administration Law, a drug manufacturer must obtain a drug manufacturing license from the provincial medical products administration authority before manufacturing drugs. Prior to granting drug manufacturing licenses, the relevant governmental authorities shall inspect the applicant's production facilities and decide whether the sanitary conditions, quality assurance system, management structure and equipment of such facilities have met the required standards. Each drug manufacturing license will be valid for five years and the manufacturer is required to apply for renewal of the license within six months prior to the expiration date and the authorities shall reassess such application of renewal in accordance with the current legal and regulatory requirements.

Drug Operation

According to the Drug Administration Law, a drug operator shall obtain a drug operation license from the provincial drug administration department before conducting the drug wholesaling or from the county's drug administration department before conducting the drug sale. On November 17, 2017, the CFDA issued the Administrative Measures for Drug Operation Licenses (《藥品經營許可證管理辦法》), which was repealed by Measures for Quality Supervision and Management of Drug Operation and Use (《藥品經營和使用質量監督管理辦法》), issued by the SAMR on September 27, 2023 and effective on January 1, 2024, which further clarify the procedure, renewal, supervision and inspection of the drug operation licenses.

Drug Advertisements

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the SCNPC in October, 1994 and last amended in April, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫療用途配方食品廣告審查管理暫行辦法》) issued by the SAMR in December, 2019 and came into effect in March, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

Good Manufacturing Practice ("GMP")

The World Health Organization encourages the adoption of GMP standards in the drug production, in order to minimize the risks of failure to pass the finished product tests in the drug production.

The MOH first issued the Guidelines on Good Manufacturing Practices (《藥品生產質量管理規範》) on March 17, 1988, which was later revised on December 28, 1992. After its establishment, the NMPA revised the Guidelines on Good Manufacturing Practices on June 18, 1999, which became effective from August 1, 1999. The Guidelines on Good Manufacturing Practices revised by the MOH on January 17, 2011, which took effect on March 1, 2011 provided the basic standards for drug production, including production facilities, qualification of management personnel, production plant and facilities, 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 Drug Administration Law Implementing Measures. 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 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 consistently in compliance with statutory requirements.

On May 24, 2021, the NMPA issued the Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) which became effective on the same day, and was amended on July 19, 2023 by the NMPA, which repealed the Administrative Measures for the Certification of Good Manufacturing Practice. The Administrative Measures for Drug Inspection (Trial) provided 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 licenses, 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.

Administrative Protection and Monitoring Periods for New Drugs

According to the Drug Administration Law Implementing Measures, to protect public health, the NMPA may provide for administrative monitoring periods of up to five years for new drugs approved to be manufactured, to consistently monitor the safety of such new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises' applications to manufacture or import a similar new drug.

REGULATIONS RELATING TO PRODUCT LIABILITY

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (i) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (ii) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (iii) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder 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.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods

and/or provide services to customers. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' personal information and must strictly keep confidential any consumer information they obtain during their business operations.

REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS

Trademarks

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013, April 23, 2019 and took effect on November 1, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and revised on April 29, 2014. In the PRC, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks. The Trademark Office of National Intellectual Property Administration handles trademark registrations and grants a term of 10 years to registered trademarks, renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term.

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) (the "**Patent Law**"), promulgated by the SCNPC on March 12, 1984 and further amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020 and came into effect on June 1, 2021 and the Implementing 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 China Patent Bureau Council on January 19, 1985, and latest amended on December 11, 2023 by the State Council and came into effect on January 20, 2024, the term "invention-creations" refers to inventions, utility models and designs. The duration of patent right for inventions shall be twenty years, the duration of patent right for utility models shall be ten years and the duration of patent right for designs shall be fifteen years, counted from the date of filing. In the event that a dispute arises due to a patent being exploited without the prior authorization of the patentee, that is to say an infringement upon the patent right of the patentee.

Internet Domain Names

The Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology of the PRC (the "**MIIT**") on August 24, 2017 and became effective on November 1, 2017, regulates the ".CN" and the ".zhongguo (in Chinese character)" shall be China's national top-level domains. Any party that engages in internet information services shall use its domain name in compliance with laws and regulations and in line with relevant provisions of the telecommunications authority but shall not use its domain name to commit any violation.

REGULATIONS ON EMPLOYMENT AND SOCIAL SECURITY

Labor Laws

The Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications.

The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and came into effect on July 1, 2013, and the Implementation

Regulations on Labor Contract Law (《中華人民共和國勞動合同法實施條例》) which was promulgated and came into effect on September 18, 2008 by the State Council, regulate the relations of employer and the employee, and contain specific provisions involving the terms of the labor contract.

Social Security and Housing Funds

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies and must pay or withhold relevant social insurance premiums for or on behalf of employees.

The PRC Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018 regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations on social insurance.

The Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated on April 3, 1999 and came into effective on the same date, and was amended on March 24, 2002 and March 24, 2019, stipulates that housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his or her employer shall all belong to the individual employee.

On July 31, 2025, the PRC Supreme People's Court promulgated the Supreme People's Court's Interpretation (II) on Several Issues Concerning the Application of Law in 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)》) (the "**New Judicial Interpretation**"), which took effect on September 1, 2025. According to the Article 19 of the New Judicial Interpretation, if an employer and an employee agree or the employee undertakes that social insurance contributions need not to be paid, the court shall deem such agreement or undertaking invalid. Where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer pursuant to Article 38(3) of the PRC Labor Contract Law, the court shall support such claims, in which case, the employer remains liable for paying economic compensation to the employee, furthermore, the court shall also support the employer's claim for the return of economic compensation previously paid to the employee, provided that the employer has made up the shortfall in such employee's social insurance contributions. As confirmed by our PRC Legal Advisors, the New Judicial Interpretation has no impact on the Company's compliance with social insurance and housing provident fund contribution requirements under relevant PRC laws and regulations, as during the Track Record Period, the Company's contributions to social insurance and housing provident fund for its employees are in compliance with relevant requirements under Social Insurance Law of the PRC and the Regulations on the Administration of Housing Provident Fund.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the "**EIT Law**"), which was promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and the Implementation Regulations on the EIT Law (《中華人民共和國企業所得稅法實施條例》), which

was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and last amended by the State Council on December 6, 2024 and came into effect on January 20, 2025, a uniform income tax rate of 25% will be applied to domestic enterprises, foreign-invested enterprises and foreign enterprises that have established production and operation facilities in China. These enterprises are classified as either resident enterprises or non-resident enterprises. Resident enterprises refer to enterprises that are established in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Non-resident enterprises refer to enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but who (whether or not through the establishment of institutions in the PRC) derive income from the PRC. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident enterprises have not established institutions or places in the PRC, or if they have established institutions or places in the PRC but there is no actual relationship between the relevant income derived in the PRC and the institutions or places set up by them, enterprise income tax is set at the rate of 10%.

Value-added Tax ("VAT")

The Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例》), which was promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例實施細則》), which was promulgated by the Ministry of Finance (the "**MOF**") on December 25, 1993 and came into effect on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011 set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

On November 16, 2011, the MOF and the State Administration of Taxation (the "**SAT**") promulgated the Trial Scheme for the Conversion of Business Tax to Value-added Tax (《營業税改徵增值税試點方案》), pursuant to which, the government launched gradual taxation reforms from January 1, 2012, where a value-added tax is imposed in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (《財政部、國家税務總局關於全面推開營業税改徵增值税試點的通知》), which was promulgated by the MOF and the SAT on March 23, 2016 and came into effective on May 1, 2016, amended on July 1, 2017, December 25, 2017 and March 20, 2019 and became effective on April 1, 2019, all business taxpayers in the consumer service industry shall pay value-added tax instead of business tax from May 1, 2016. If the taxpayer of the pilot project has already enjoyed tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax in lieu of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions. Medical services provided by medical institutions shall be exempted from value-added tax.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、國家税務總局關於調整增值税税率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the value-added tax rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Notice on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值税改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, which was partially abolished in August 22, 2015, the value-added tax rate was reduced to 13% and 9%, respectively.

On December 25, 2024, the SCNPC promulgated the Value-added Tax Law of the PRC, which will become effective on January 1, 2026, and replace the Provisional Regulations on Value-added Tax of the PRC.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the State Administration of Foreign Exchange of the PRC (the "**SAFE**") issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》), or the SAFE Circular 59, which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, multiple capital accounts for the same entity may be opened in different provinces as well. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was partially abolished in December 2019, prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), or the SAFE Circular 21, which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or the SAFE Circular 19 promulgated on March 30, 2015, coming effective on June 1, 2015 and partially

abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《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》), or the SAFE Circular 16, which came into effect on the same day and partially amended on December 4, 2023 and effective since then. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16's interpretation and implementation in practice.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020), and partially amended on December 4, 2023 and effective since then. The notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without submitting the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use is authentic and in compliance with administrative regulations on the use of income under capital accounts. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

REGULATIONS ON THE COMPANIES AND FOREIGN INVESTMENT IN CHINA

The Company Law and Regulations

The Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"), which was last amended by the SCNPC on December 29, 2023 and became effective on July 1, 2024, provides for the establishment, corporate structure and corporate management of companies, which also applies to foreign-invested enterprises in PRC.

Regulations relating to Foreign Investment

On March 15, 2019, the NPC promulgated the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**"), which took effect on January 1, 2020 and repealed the Sino-foreign Equity Joint Ventures Law of the PRC (《中華人民共和國中外合資

經營企業法》), the Wholly Foreign-owned Enterprise Law of the PRC (《中華人民共和國外資企業法》) and the Sino-foreign Cooperative Joint Ventures Law of the PRC (《中華人民共和國中外合作經營企業法》). Since then, the Foreign Investment Law has become the fundamental 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 and effective from January 1, 2020, foreign investment refers to any investment activity directly or indirectly carried out by foreign natural persons, enterprises or other organizations (the "**foreign investors**") within the territory of the PRC, including the following circumstances: (i) a foreign investor establishes a foreign-funded enterprise within the territory of the PRC, either alone or together with any other investor; (ii) a foreign investor acquires shares, equities, property shares or any other similar rights and interests of a PRC enterprise; (iii) a foreign investor invests in any new project within the territory of the PRC, either alone or together with any other investor; or (iv) a foreign investor invests in any other way as stipulated under the laws or administrative regulations or provided by the State Council. The organization form and structure, and the operating rules of foreign-funded enterprises are subject to the provisions of the Company Law, the Partnership Enterprise Law of the PRC and other applicable laws.

Pursuant to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) promulgated by the Ministry of Commerce of the PRC (the "**MOFCOM**") and the SAMR on December 30, 2019 and effective on January 1, 2020, a listed foreign-funded company may, when the change of foreign investors' shareholding ratio accumulatively exceeds 5% or the foreign party's controlling or relatively controlling status changes, report the information on the modification of investors and the shares held by them.

REGULATIONS ON OVERSEAS LISTING

The CSRC promulgated the Trial Measures and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Trial Measures comprehensively reform the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system.

According to the Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Trial Measures provide that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in PRC laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller. According to the Trial Measures, initial public offerings or listings in overseas markets shall be filed with the CSRC within three working days after the relevant application is submitted overseas.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing 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》) (the "**Provision on Confidentiality**"), which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory

authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing. Domestic enterprises providing accounting archives or copies thereof to entities and individuals concerned such as securities companies, securities service institutions and overseas regulatory authorities shall perform the corresponding procedures pursuant to the relevant provisions of the State. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and those that need to leave the PRC shall go through the examination and approval formalities in accordance with the relevant provisions of the State.

REGULATIONS ON CYBERSECURITY AND DATA EXPORTATION SECURITY

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Measures for Cybersecurity Review**"), which became effective on February 15, 2022, 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.

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》) (the "**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 10,000 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".

REGULATIONS ON STOCK INCENTIVE PLANS

On February 15, 2012, SAFE promulgated the Notice on Foreign Exchange Administration of PRC Residents Participating in Share Incentive Plans of Offshore Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules. According to the Stock Option Rules, individuals participating in any stock incentive plan of any overseas publicly listed company who are Chinese citizens or foreign citizens who reside in mainland China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE or its local branches and complete certain other procedures through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain other procedures. The participants must also retain

an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase, and sale of corresponding stocks or interests, and fund transfers. In addition, the agent in mainland China is required to further amend the SAFE registration concerning the stock incentive plan if there is any material change to the stock incentive plan, the mainland Chinese agent or the overseas entrusted institution, or other material changes. The mainland Chinese agents must, on behalf of the mainland Chinese residents who have the right to exercise the employee share options, apply to SAFE or its local branches for an annual quota for the payment of foreign currencies in connection with the mainland Chinese residents' exercise of the employee share options. The foreign exchange proceeds received by the mainland Chinese residents from the sale of shares under the stock incentive plans granted and dividends distributed by the overseas-listed companies must be remitted into the bank accounts in mainland China opened by the mainland Chinese agents before distribution to such mainland Chinese residents. Under the Circular of the State Administration of Taxation on Issues Concerning Individual Income Tax concerning Equity Incentives (《國家税務總局關於股權激勵有關個人所得税問題的通知》) promulgated by the SAT and effective on August 24, 2009, listed companies and their domestic organizations shall, according to the individual income tax calculation methods for "wage and salary income" and stock option income, lawfully withhold and pay individual income tax on such income.

U.S. AND EUROPEAN LAWS AND REGULATIONS

Regulations on siRNA Therapeutics

The regulatory landscape for siRNA therapeutics continues to evolve as regulators refine product-specific expectations for oligonucleotide drugs.

In June 2024, the FDA issued the final draft of "Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics," providing recommendations to assist industry in the development of oligonucleotide therapeutics under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR parts 312 and 314. Specifically, this guidance delineates the FDA's expectations for certain evaluations during development of oligonucleotide therapeutics — including characterization of QTc interval prolongation risk, immunogenicity risk assessment, evaluation of hepatic and renal impairment effects, and drug-drug interaction assessment — and clarifies both the appropriate timing and recommended types of assessments for each area.

In November 2024, the FDA announced the draft guidance for industry entitled "Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics," which, when finalized, will provide recommendations on approaches for the nonclinical safety evaluation of oligonucleotide-based therapeutics (ONTs) to support their clinical development and marketing. The draft guidance recognizes that ONTs pose unique challenges and opportunities in nonclinical safety evaluation that differ in many respects from those relevant to small molecule drugs or therapeutic proteins.

In July 2024, the EMA released the draft "Guideline on the Development and Manufacture of Oligonucleotides," which remained under public consultation until January 31, 2025. This is the first comprehensive regulatory framework in the EU dedicated specifically to synthetic oligonucleotides, including siRNA therapeutics. The guideline addresses aspects of manufacturing, characterization, specification setting, and analytical control that are not fully covered by existing EMA or ICH guidance, including ICH Q3A/B, ICH Q6A/B, and ICH M7, due to the distinctive physicochemical properties and manufacturing processes of oligonucleotides. The guideline provides detailed expectations for solid-phase synthesis, strand annealing, impurity profiling, stereochemical characterization of phosphorothioate linkages, and the use of orthogonal analytical methods. It further addresses control of singlestranded intermediates and duplex purity, requirements for conjugates such as GalNAc, and considerations for active substances in solution and clinical trial applications. mRNA products fall outside the scope of this guideline.

The BIOSECURE Act

On December 18, 2025, the BIOSECURE Act became law as part of the Fiscal Year 2026 National Defense Authorization Act. The BIOSECURE Act prohibits U.S. executive agencies from contracting with or providing funds to "Biotechnology Companies of Concern" (BCOCs), which include entities on the Department of Defense's "1260H List" of Chinese military companies operating in the United States, as well as other companies designated by the Office of Management and Budget (OMB) through specified risk criteria.

The BIOSECURE Act also introduces notable changes from previous drafts. Unlike earlier proposals, the final legislation does not automatically cover all affiliates of designated companies, thereby reducing the likelihood of including unrelated entities. In addition, the compliance burden on federal contractors is eased by requiring actual knowledge — rather than "reason to believe" — that a contract would involve a BCOC, reducing the risk of inadvertent violations for companies with large or complex supply chains.

The BIOSECURE Act's requirements are designed for phased implementation, including transition periods, grandfathering for existing agreements, and targeted exemptions. OMB must publish its initial list of BCOCs within one year, to be followed by implementing guidance and Federal Acquisition Regulation (FAR) updates on a set timeline. In practice, the full restrictions may not take effect for up to 970 days (about 2 years and 8 months) after enactment for 1260H List companies, with slightly more time for entities later designated by OMB. A five-year transition window applies to existing contracts, except for those tied to the 1260H List, for which restrictions take effect much sooner.