OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

DRUG REGULATORY REGIME

Major Regulatory Authorities

The drug industry in the PRC is mainly administered by three governmental agencies: the National Medical Product Administration (國家藥品監督管理局) (the "**NMPA**"), a department under the State Administration for Market Regulation (國家市場監督管理總局), the National Health Commission (國家衛生健康委員會) (the "**NHC**") and the National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**").

The NMPA, which inherits the drug supervision function from its predecessor the China Food and Drug Administration, or the CFDA (before March 2018), is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical researches, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

The NHC, formerly known as the National Health and Family Planning Commission, is China's chief healthcare regulator. It is primarily responsible for drafting national healthcare policy and regulating public health, medical services, and health contingency system, coordinating the healthcare reform, and overseeing the operation of medical institutions and practicing of medical personnel.

The NHSA, a new authority established in May 2018, is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare fund; formulating a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

Reform of the Drug Approval System

On August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) (the "**Reform Opinions**"), which established a framework for reforming the evaluation and approval system for drugs and medical devices. The Reform Opinions indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

On March 4, 2016, the General Office of the State Council promulgated the Guiding Opinions on Promoting the Sound Development of the Medical Industry (《關於促進醫藥產業健康發展的指導意見》), which aims to accelerate the development of innovative drugs and biological products with major clinical needs, to speed up the promotion of green and intelligent pharmaceutical production technologies, to strengthen scientific and efficient supervision, and to promote the development of industrial internationalization.

On October 8, 2017, the General Office of Chinese Communist Party's Central Committee and the General Office of the State Council jointly issued the Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《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》) (the "**Innovation Opinion**"), which seek to streamline the clinical trial process and shorten the timeline. The Innovation Opinion provided special fast-track approval for new drugs and medical devices in urgent clinical need, and drugs and medical devices for rare diseases.

On December 21, 2017, the CFDA promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast-track clinical trial approval or drug registration pathway will be available to innovative drugs. The aforementioned opinion was repealed by the Announcement of NMPA on Issuing Three Documents including Working Procedures for Review of Breakthrough Therapeutics (Trial) (issued and took effect on July 7, 2020) (《國家藥監局關於發佈<突破性治療藥物審評工作程序(試行)>等三個文件的公告》).

On May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《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 clinical trial approval process.

Regulations in relation to the Registration of New Drugs

Non-Clinical Research and Animal Testing

The non-clinical safety evaluation study for drugs for the purpose of applying for marketing approval shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Drug Research (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and revised on July 27, 2017 by the CFDA. On April 16, 2007, the CFDA issued the Administrative Measures for the Certification of Good Laboratory Practices for Non-Clinical Drug Research (《藥物非臨床研究質量管理規範認證管理辦法》), which sets forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake drug non-clinical research.

The State Science and Technology Commission, now known as the Ministry of Science and Technology, promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) on November 14, 1988, which were most recently amended by the State Council on March 1, 2017. The State Science and Technology

Commission and the State Bureau of Quality and Technical Supervision (now merged into the State Administration for Market Regulation) jointly promulgated the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) on December 11, 1997. The Ministry of Science and Technology and other regulatory authorities promulgated the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) on December 5, 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

Clinical Trial Application

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Registration Measures**"), which was promulgated on January 22, 2020 and took effect on July 1, 2020, the Center for Drug Evaluation under the NMPA (the "**CDE**") is responsible for the application of conducting new drug clinical trials. According to Registration Measures, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued on July 24, 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 business days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the clinical trial authorization from the NMPA, the applicant must register the clinical trial at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect on September 6, 2013. The applicant shall complete the initial registration within one month after obtaining the clinical trial authorization and complete follow-up registrations before the first subject's enrollment in the trial.

Conduction of Clinical Trial and the Communication with CDE

Clinical trials must be conducted in accordance with the Announcement on Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), which was promulgated by the NMPA and NHC on April 23, 2020 and took effect on July 1, 2020, which also sets forth the requirements for conducting the clinical trial, including preparation of clinical trials, clinical trial protocol, duties of the sponsor and investigators and protection of the trial subjects.

The drug clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements of the Good Clinical Practice for Drug Trials (the "**GCP**") and relevant technical guidelines for clinical trials according to the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which was promulgated by the NMPA and NHC on November 29, 2019 and came into effect on December 1, 2019.

On September 1, 2003, the Good Practice for Clinical Trial of Drugs (藥物臨床試驗質量管理規範) promulgated by the CFDA came into effect, and was later repealed by Good Practice for Clinical Trial of Drugs (Revised in 2020) (藥物臨床試驗質量管理規範(2020修訂), together the "**GCP**") on July 1, 2020. According to the GCP, the drug clinical trials shall be commenced after the approval of the Ethics Committee.

On November 11, 2015, CFDA published the Circular Concerning Several Policies on Drug Registration, Review and Approval (CFDA Announcement No. 230 of 2015) (《關於藥品註冊審評審批若干政策的公告》(國家食品藥品監督管理總局2015年第230號公告)), according to which, clinical trial applications for new drugs shall be approved on a one-off basis, and will no longer be filed in stages and reviewed and approved in stages. According to such announcement, the state changed the original drug clinical trial approval issued separately for each phase of the drug clinical trial to one approval that can cover Phase I to Phase III clinical trials.

On June 2, 2016, CFDA published the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (Trial) (《藥物研發與技術審評溝通交流管理辦法(試行)》) (the "**Communication Measures (Trial)**"). On September 30, 2018, the Communication Measures (Trail) was repealed by the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》, the "**Communication Measures 2018**") published by NMPA, which added several scenarios where communication with CDE is possible (but not mandatory), such as adding clinical trial applications for new indications.

On July 1, 2020, the Registration Measures promulgated by the State Administration for Market Regulation came into effective, according to which, clinical trials shall be reviewed and approved by the Ethics Committee. The applicant shall develop a clinical trial protocol prior to the commencement of subsequent phases of clinical trials, which shall be reviewed and approved by the ethics committee, and the applicant shall submit the corresponding clinical trial protocol and supportive information on the designated website of CDE prior to the commencement of the clinical trial. Meanwhile, Registration Measures also incorporates the communication system into the fundamental system for drug registration management, and proposes that the applicant may communicate with CDE and other professional and technical institutions on major issues prior to the clinical trial application, during the course of the clinical trial, prior to the marketing approval application and other key stages, and shall consult with CDE under special circumstances.

On December 10, 2020, NMPA published the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》) (the "**Communication Measures (2020)**") to repeal the Communication Measures 2018. To better reflect the service nature of communication and on the basis of ensuring the safety of the subjects of the clinical trials, the Communication Measures (2020) classifies the meetings to be held in the key stages of drug research and development into three scenarios, namely (i) where communication shall be carried out in accordance with the law; (ii) where communication shall be carried out in principle; and (iii)

where communication can be carried out. Specifically, (i) as to the application for conditional approval and/or the application of priority review, the applicant shall consult and confirm with CDE in accordance with the law prior to submitting applications for marketing approval to NMPA; (ii) prior to the application of the first new drug clinical trials, and the application for marketing approval of biological products for prevention and therapeutic use, the applicant shall in principle consult CDE, but if the applicant believes that there is no need to consult, it can explain the reason for which in application materials; (iii) as to all other scenarios, the applicant can consult CDE but are not specifically required to.

To implement the research and development concept driven by clinical value and centered on the need of patients, and to promote the scientific and orderly development of anti-tumor drugs, the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則(徵求意見稿)》) was issued by the CDE on July 2, 2021, and later on November 15, 2021, upon NMPA's review and approval, the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) (No. 46[2021], the "**Guiding Principles**") was officially released and implemented by CDE. According to the Registration Measures, persons engaging in drug development and drug registration activities shall comply with the relevant laws, regulations, rules, standards and norms; with reference to the relevant technical guidelines formulated and published by the CDE and other specialized technical agencies, therefore, the Guiding Principle is a one of the various technical guidelines issued by CDE for the reference of the applicant in the process of drug development. The Guiding Principles aim to put forward suggestions on the clinical research and development of anti-tumor drugs from the perspective of patients' needs, with a view to guiding applicants of anti-tumor drug clinical trials to implement the research and development concept driven by clinical value and centered on the need of patients during its research and development activities, and providing references for promoting the scientific and orderly development of anti-tumor drugs. The Guiding Principles do not discuss any specific methodologies.

As of the Latest Practicable Date, we had obtained the New Drug Certificate for our Core Product and put it on the market for sale, and we had obtained required clinical trial approvals for the candidate drugs at the clinical stage. Besides, we will design the clinical trial protocols according to the Guiding Principles and obtain the clinical trial approvals before conducting new clinical trials. Given our strong R&D team and extensive experience in the field of anti-tumor drugs, we believe that we will continue to adhere to the principles proposed in the Guiding Principles, and our Directors confirm that the Guiding Principles will not have any material adverse impact on our business and operations.

Regulations relating to International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》) (the "**IMCT Guidelines**"), which took effect on March 1, 2015, to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the IMCT Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to the CFDA for approval of New Drug Application (the "**NDA**"), such international multi-center clinical trials shall satisfy the requirements set forth in the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and its implementation regulations and relevant laws and regulations.

On July 6, 2018, the NMPA issued the Technical Guiding Principles for the Acceptance of the 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》) (the "**Guiding Principles**"), which provides that overseas clinical data can be submitted for all kinds of registration applications in China, including the clinical trial authorization and NDA. The Guiding Principles clearly list the basic principles and requirements on the acceptance of overseas clinical trial data, and distinguish different levels of acceptance based on the quality of the data itself and different circumstances. The Guiding Principles require that the applicant shall ensure that the overseas clinical trial data are truthful, complete, accurate and traceable, and the generating process of the overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

New Drug Application

Pursuant to the Registration Measures, upon completion of clinical trials, 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 to the NMPA for approval of NDA. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain approval of NDA before the drugs can be manufactured and sold in the China market. According to the Registration Measures, for (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm the efficacy and forecast the clinical value of the drugs; (2) drugs which are urgently needed for public health and data of clinical trials can reveal the efficacy and forecast the clinical value of the drugs; (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and the benefit is assessed outweigh the risk, such drugs can apply for conditional approval.

Reclassification of Drugs

On March 4, 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) (the "**Drug Reclassification Plan**"), which outlined the reclassifications of drug applications. Under the Drug Reclassification Plan, Category 1 refers to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad but are not yet approved in China. The Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) which was promulgated by NMPA on June 29, 2020, and took effect on July 1, 2020 (for the chemical drug registration classification part) and October 1, 2020 (for the chemical drug registration application data requirements part), reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

On June 29, 2020, the NMPA issued the Registration Category of Biological Products and the Data Requirements for Declaration (《生物製品註冊分類及申報資料要求》), which took effect on July 1, 2020 stipulated that the therapeutic biological products should be classified into 3 categories, in which Category 1 refers to therapeutic biological products that have not been marketed anywhere in the world; Category 2 refers to improved new therapeutic biological products; and, Category 3 refers to therapeutic biological products that have been marketed in China or abroad.

Prioritized Examination and Approval for Registration of Certain Drugs

On November 11, 2015, the CFDA promulgated the Circular Concerning 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》), which provides that a fast-track clinical trial approval or drug registration pathway can be available for the applications for certain drugs, including the registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases, and registration of pediatric drugs, etc.

On July 7, 2020, the NMPA promulgated the Announcement on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation) (《國家藥監局關於發佈<突破性治療藥物審評工作程序(試行)>等三個文件的公告》), which stipulates that during the clinical trial period, innovative drugs or modified new drugs that are used to prevent and treat the disease that is serious life-threatening or severely affecting the quality of life and there is no effective prevention and treatment method, or compared with existing treatment methods that have sufficient evidence to show that they have obvious clinical advantages, then any applicant can apply for breakthrough therapeutic drug programs during Phase I and II clinical trials, but usually no later than the commencement of Phase III clinical trials.

In addition, on May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《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 approval process.

Special Examination and Approval Procedures

On November 18, 2005, the CFDA promulgated the Procedures of the CFDA for the Special Examination and Approval of Drugs (《國家食品藥品監督管理局藥品特別審批程序》), which stipulates that in the case of any threatening or actual public health emergency, the CFDA shall take a series of measures to facilitate the approval procedures so that the drugs needed in responding to the public health emergency can be approved as soon as possible.

Marketing Authorization Holder System

Under the authorization of the Standing Committee of the National People's Congress, the General Office of the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder System (《藥品上市許可持有人制度試點方案》) on May 26, 2016, which provides a detailed pilot plan for the marketing authorization holder system, or MAH System, for drugs in 10 provinces (cities) in China and the plan ended on November 4, 2018. The pilot period was later extended to November 4, 2019 by the SCNPC.

Pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), which was promulgated on September 20, 1984 by the Standing Committee of the National People's Congress and recently revised on August 26, 2019 and took effect on December 1, 2019, the MAH system will be applicable throughout the country. Under the MAH System, domestic drug research and development institutions and enterprises are eligible to be holders of drug registrations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs. And holders of drug registrations shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the quality of medicines management.

Sampling and Collecting Human Genetic Resources Filing

On June 10, 1998, the Ministry of Science and Technology and the Ministry of Health promulgated the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which established the rules for protecting and utilizing human genetic resources in the PRC. According to the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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 the Circular on Implementing the Administrative Licensing for the Sampling, Collection, Trading, Exporting of Human Genetic Resources, or Taking Such Resources out of PRC (《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, the sampling

and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, 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》) simplifying the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

The Regulations of the PRC on the Administration of Human Genetic Resources promulgated by the State Council on May 28, 2019 (《中華人民共和國人類遺傳資源管理條例》) and came into effect on July 1, 2019 repealed the Interim Administrative Measures on Human Genetic Resources, and further stipulates that 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 exporting of human genetic resource materials. However, the two parties shall file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials.

On October 17, 2020, the *PRC Biosecurity Law* (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") was promulgated by Standing Committee of the National People's Congress, taking effect from April 15, 2021. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbials laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC, upon obtaining the approval or record-filing; the establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law; (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 department of science and technology under the State Council, (ii) preserving the PRC's human genetic resources, (iii) using the PRC's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying the PRC's human genetic resource materials out of the country shall subject to approval of the competent department of science and technology.

Administrative Protection and Monitoring Periods for New Drugs

The PRC Drug Administration Law is the framework law regulating pharmaceutical products and the industry. According to the Implementing Rules for PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) issued on March 2, 2019 and the Drug Reclassification Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not accept other applications for new drugs containing the same active ingredient.

Regulations in relation to the Manufacturing of Drugs

Drug Manufacturing Permit

Pursuant to the PRC Drug Administration Law, a drug manufacturer must obtain a Drug Manufacturing Permit from the NMPA before it starts to manufacture drug products. Prior to granting such permit, the relevant government authority will inspect the applicant's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards. Each Drug Manufacturing Permit is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then-prevailing legal and regulatory requirements for the purposes of such renewal.

Good Manufacturing Practice

Pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA on August 2, 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer must apply for Good Manufacturing Practice certification (the "**GMP certification**"). The drug manufacturer that has obtained the GMP certificate should reapply for the GMP certificate 6 months prior to its expiration date. Pursuant to the PRC Drug Administration Law, since December 1, 2019, the GMP certification has been canceled, applications for GMP certification are no longer accepted, and GMP certificate is no longer issued, but drug manufacturers are still required to comply with the GMP rules. According to the Administrative Measures for the Inspection of Pharmaceuticals (Trial)(《藥品檢查管理辦法(試行)》)which was promulgated and effective on May 24, 2021 by the NMPA, and simultaneously repealed the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》), if a drug manufacturing enterprise applies for a Drug Manufacturing Permit for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturing enterprise applies for re-issuance of Drug Manufacturing Permit, drug regulatory departments or drug inspection institutions shall

conduct examination pursuant to risk management principle, taking into account the enterprise's compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

The drug manufacturer must conduct the manufacturing process according to the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (2010 version) issued by the Ministry of Health on January 17, 2011, which sets forth the requirements on the manufacturer's organization and staff qualifications, manufacture premises and facilities, equipment, hygiene conditions, manufacture management, product management, maintenance of sales records and the procedure of handling customer complaints and adverse reaction reports.

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) issued by the CFDA on August 14, 2014 (the "**Contract Manufacturing Regulations**"), in the event a drug manufacturer in China that has obtained a drug marketing authorization temporarily lacks manufacturing conditions as a result of technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, it can entrust the manufacturing of that drug to another domestic drug manufacturer. Such contract manufacturing arrangements need to be approved by the provincial branch of the CFDA. The Contract Manufacturing Regulations prohibit the contract manufacturing arrangement of certain special drugs, including narcotic drugs, psychoactive drugs, biochemical drugs and active pharmaceutical ingredients.

According to the PRC Drug Administration Law, a drug manufacturer can entrust the manufacturing of its drug to another qualified drug manufacturer. Entrusted manufacturing of blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals is prohibited, unless otherwise stipulated by the drug administrative department of the State Council.

The PRC Drug Administration Law specifies that drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs. A drug marketing authorization holder that intends to manufacture drugs on its own shall obtain a drug manufacturing permit; if it intends to manufacture drugs on a commissioned basis, it shall entrust a qualified drug manufacturer. Drug marketing authorization holders and the commissioned manufacturers shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations under such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the department of drug supervision and administration of the State Council.

Regulations in relation to Drug Distribution and Advertising

Drug Distribution

According to the PRC Drug Administration Law and the Measures for the Supervision and Administration of Drug Distribution (《藥品流通監督管理辦法》) issued by the CFDA on January 31, 2007 and came into effect on May 1, 2007, drug enterprises shall be responsible for the quality of drugs they manufacture, distribute or use, purchase, sell, transport or store, and drug distributors must obtain the Drug Operation Permit.

According to the Measures on the Administration of Drug Operation Permit (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and amended on November 17, 2017 by the CFDA, a Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit six months prior to expiration, and extensions are granted only after a reexamination of the permit holder by the authority which issued the permit.

Good Supply Practices

According to the Good Supply Practice for Drugs (《藥品經營質量管理規範》) (the "**Good Supply Practice**") promulgated by NMPA on April 30, 2000 and last amended on July 13, 2016, drug distributors shall strictly implement the Good Supply Practice. Enterprises shall take effective measures for quality control at such stages as procurement, storage, sales and transportation of drugs to ensure the quality of drugs and shall develop a drug traceability system as per relevant requirements of the state to realize the traceability of drugs. In addition, the CFDA revised the Guidelines for On-site Inspection of Drug Operation and Quality Management Specifications (《藥品經營質量管理規範現場檢查指導原則》) in 2016, in order to further regulate the organization of the supervision and inspection of drug distributors.

Advertising of Drugs

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the Standing Committee of the National People's Congress on October 27, 1994 and last amended on April 29, 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、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the State Administration for Market Regulation on December 24, 2019 and came into effect on March 1, 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.

Price Controls and Two-invoice System

Instead of direct price controls which were historically used in China, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

According to the Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) promulgated on July 7, 2000 and the Notice of NMPA on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《國家藥品監督管理局關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated on July 23, 2001, not-for-profit medical institutions established by county or higher level government are required to implement centralised tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. According to the Notice of the Financial Planning Department of Ministry of Health on Issue of Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (《衛生部財務規劃司關於印發<進一步規範醫療機構藥品集中採購工作的意見>的通知》) promulgated on January 17, 2009, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalogue of drugs subject to centralised procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated on January 24, 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralised Procurement and Use of the Drug Organised by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated on January 1, 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralised tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralised tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the "two-invoice system" (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)的通知》), or the Two-Invoice System Notice, which came into effect on December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the medical institution, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the medical institution.

According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reforming and Improving the Policies on Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, the two-invoice system would be promoted in pilot provinces (or autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, and encouraged to be implemented nationwide in 2018.

Regulations in relation to Intellectual Properties

Patent

Patents in the PRC are mainly protected under the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the Standing Committee of the National People's Congress on March 12, 1984 and amended on September 4, 1992, August 25, 2000, December 27, 2008 and October 17, 2020, and its Implementation Rules (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and most recently amended on January 9, 2010. The Patent Law and its Implementation Rules provide for three types of patents, "invention," "utility model" and "design." "Invention" refers to any

new technical solution relating to a product, a process or improvement thereof; "utility model" refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and "design" refers to any new design of the whole or part of the shape, pattern, their combination, or the combination of color and shape or pattern, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for "invention" is 20 years, the duration of a patent right for "design" is 15 years and the duration of a patent right for "utility model" is 10 years, from the date of application. The new Patent Law of the PRC provides a patent term extension for new drugs, according to which, new drugs may enjoy a compensation for the duration of patent rights which is up to 5 years, and the total patent term after the extension may not exceed more than 14 years from the date of marketing approval of the new drugs.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) (the "**Trademark Law**"), promulgated by the Standing Committee of the National People's Congress on August 23, 1982 and most recently amended on April 23, 2019 and took effect on November 1, 2019, 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 twelve 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 cancelled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offence, the case shall be timely referred to a judicial authority and decided according to law.

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the Standing Committee of the National People's Congress on September 2, 1993 and most recently amended on April 23, 2019, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, businesses are prohibited from infringing others' trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other improper means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another 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; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her

non-disclosure obligation of the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Domain Names

Domain names are protected under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017 and took effect on November 1, 2017, and the *Implementing Rules of China ccTLD Registration* (《國家頂級域名註冊實施細則》) issued by the China Internet Network Information Center on June 18, 2019. MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Regulations in relation to Product Liability and Tort

According to the General Principles of the Civil Law of the PRC (《中華人民共和國民法通則》) promulgated on April 12, 1986 and amended on August 27, 2009 and the General Rules of the Civil Law of the PRC (《中華人民共和國民法總則》) promulgated on March 15, 2017 and took effect on October 1, 2017, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the Standing Committee of the National People's Congress on February 22, 1993 and most recently amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality, which clarified liabilities of the manufactures and sellers. Manufactures shall not be liable when they are able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall pay compensation if it fails to indicate neither the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

According to the Tort Liability Law of the PRC (《中華人民共和國侵權責任法》), promulgated by the Standing Committee of the National People's Congress on December 26, 2009 and took effect on July 1, 2010, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. Sellers shall assume tort liability where the defects in relevant products causing damage to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant

product in which the defects have caused damage. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

On May 28, 2020, the National People's Congress promulgated the Civil Code of the PRC (《中華人民共和國民法典》) which became effective on January 1, 2021 and simultaneously repealed the General Principles of the Civil Law of the PRC, the General Rules of the Civil Law of the PRC and the Tort Law of the PRC, according to which, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

Regulations in relation to Company Establishment and Foreign Investment

Company Establishment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"), which was promulgated by the Standing Committee of the National People's Congress on December 29, 1993 and came into effect on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. Pursuant to the Company Law, companies are classified into 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.

The Company Law is the principal law governing dividend distributions of PRC companies. PRC companies may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting principles. In addition, PRC companies are required to set aside each year at least 10% of their after-tax profit based on PRC accounting principles to their statutory general reserves funds until the cumulative amount of such reserve fund reaches 50% of their registered capital. These reserves or funds are not distributable as dividends. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year. Upon approval of the competent governmental authorities, foreign investors may utilize RMB dividends to invest or re-invest in enterprises established in China.

Foreign Direct Investment

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**FIL**"), which was promulgated by the National People's Congress on March 15, 2019 and came into effect on January 1, 2020, and the Regulations for Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which was promulgated by the State Council on December 26, 2019 and came into effect on January 1, 2020, the foreign investment refers to the investment activities in China carried out directly or indirectly by foreign natural persons, enterprises or other organizations, including the following: (1) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (2) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (3) Foreign Investors investing in new projects in China alone or collectively with other investors; and (4) Foreign Investors investing through other ways prescribed by laws and regulations of the State Council. The State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The pre-establishment national treatment refers to granting to Foreign Investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State will grant national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council.

Foreign investment in China is subject to the Catalogue for the Encouraged Investment Industries (2020 Edition) (《鼓勵外商投資產業目錄(2020年版)》) issued on December 27, 2020 and took effect on January 27, 2021, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021 Edition) (《外商投資准入特別管理措施(負面清單)》) (2021年版) issued on December 27, 2021 and took effect on January 1, 2022, which together comprise the encouraged foreign-invested industries catalogue and the special administrative measures for the access of foreign investments to the restricted or the prohibited foreign-invested industries. The latter sets out restrictions such as percentage of shareholding and qualifications of senior management. According to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) which took effect on January 1, 2020, foreign investments that are not subject to special access administrative measures are only required to complete an online filing to the commerce departments.

Regulations on Data Security

The Cyberspace Administration of China ("**CAC**"), jointly with the other 12 governmental authorities, promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》) on December 28, 2021, which became effective on February 15, 2022. Pursuant to Article 2 of the Cybersecurity Review Measures, to ensure the security of the supply chain of critical information infrastructure, security of network and data and safeguard national security, a cybersecurity review is required when national security has been or may be affected where critical information infrastructure operators (關鍵信息基礎設施運營者) purchase network product or service and network platform operators (網絡平台運營者) conduct data process activities. In addition, Article 7 of the Cybersecurity Review Measures stipulates that when a network platform operator in possession of personal information of over one million users intends to "list abroad" (國外), it must apply to CAC for a cybersecurity review. Our Directors believe that, as of the Latest Practicable Date, (i) the Company has not been determined or identified as a critical information infrastructure operator by any governmental authorities; (ii) the Company has not engaged in any data processing activities that affect or may affect national security; and (iii) the Company has not been involved in any investigations on cybersecurity review initiated by CAC, and has not received any inquiry, notice, warning or sanctions in this regard.

Based on the above, our PRC Legal Advisers are of the view that (1) it is unlikely that the Company would be determined or identified as a critical information infrastructure operator as long as there is no material change to the Group's current business; and (2) given the expression used in the Cybersecurity Review Measures is to "list abroad" and the fact that Hong Kong is not a country or region outside the PRC, as long as there is no specific official guidance or implementation rules to include Hong Kong in the scope of "abroad" in the future, the Company's proposed [**REDACTED**] in Hong Kong is unlikely to be considered as to "list abroad". Therefore, the Company has no obligation to proactively apply for cybersecurity review under the Cybersecurity Review Measures for its application of the proposed [**REDACTED**] in Hong Kong.

On November 14, 2021, the CAC released the Regulations on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the "**Draft Regulations**"). The Draft Regulations applies to data processing activities by utilizing internet as well as cyber data security supervision and management activities within the PRC. Under the Draft Regulations, "Cyber data" refers to any information that is electronically recorded, whereas "data processing activities" refers to activities such as data collection, storage, usage, processing, transmission, provision, disclosure and deletion. In general, any company which is engaged in data processing activities through internet within the PRC will be subject to the Draft Regulations. As advised by our PRC Legal Advisers, by collecting, storing and otherwise processing certain information via internet in connection with its business operations, the Group could be subject to relevant requirements under the Draft Regulations in terms of personal data protection, cyber security management, assessment and report and other applicable aspects, assuming such regulation is implemented in the current form.

Article 13 of the Draft Regulations stipulates that data processors shall apply for cybersecurity review when carrying out activities including (i) seeking to be listed in Hong Kong that affect or may affect national security; and (ii) other data processing activities that affect or may affect national security. Our Directors believe that the Group has not engaged in any data processing activities that affect or may affect national security and thus the Company is unlikely to be deemed as a data processor that affect or may affect national security. Given that the Draft Regulations is still in the draft form for comments and has not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Regulations is still subject to further official guidance and applicable implementation rules.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》, the "**Security Assessment Measures**"), which was promulgated by the CAC on July 7, 2022 and came into effect on September 1, 2022, data processors shall apply for cross-border security assessment with the CAC through the local provincial-level cyberspace administration department under any of the following circumstances: (i) cross-border transfer of important data by data processors; (ii) cross-border transfer of personal information by critical information infrastructure operators and data processors that process more than 1 million personal information; (iii) cross-border transfer of personal information by data processors that have made cross-border transfer of personal information of 100,000 people or sensitive personal information of 10,000 people cumulatively since January 1 of the previous year; and (iv) other circumstances where an application for security assessment of cross-border data transfer is required as prescribed by the CAC.

Based on the telephone consultation conducted by the Company and its PRC Legal Advisers with CAC on real-name basis, CAC confirmed that (i) the Company is not required to apply for cybersecurity review with respect to the Company's proposed [**REDACTED**] in Hong Kong under Cybersecurity Review Measures; (ii) as the Draft Regulations was still in the draft form for comments and had not come into effect, the Company was not required to take any actions to comply with the requirements under the Draft Regulations, nor was CAC in a position to provide any interpretation, explanation or comments on the Draft Regulations at the time of the consultation. As confirmed by our Directors, the Company had not received any data security related enquiries, or enquiries in relation to any other matters, and/or invitation for interviews from any competent authorities as of the date of this document.

Our Group is able to comply with the Cybersecurity Review Measures and the Draft Regulations assuming they are implemented in their current form, in all material aspects on the basis that (i) we have implemented comprehensive cyber security and data protection policies, procedures, and measures to ensure secured storage and transmission of data and prevent unauthorized access to or use of data, and our Directors are of the view that our Group's current internal policies are in line with such requirements specified in the Cybersecurity Review Measures and the Draft Regulations as currently stipulated; (ii) as confirmed by our Internal Control Consultant, our Group has set up internal control policies in terms of personal information and data protection and cybersecurity in accordance with currently applicable laws and regulations; and (iii) as confirmed by our Directors, we will continuously pay close attention to the legislative and regulatory development in cybersecurity and data protection,

maintain ongoing communication with relevant governmental authorities and implement all necessary measures in a timely manner to ensure continuous compliance with relevant laws and regulations. Based on the above, our PRC Legal Advisers are of the view that the Cybersecurity Review Measures and the Draft Regulations would have no material adverse impact on our Group's business operations or our proposed [**REDACTED**] in Hong Kong, assuming the Cybersecurity Review Measures and the Draft Regulations are implemented in their current form.

Foreign Exchange Administration

The principal law governing foreign currency exchange in the PRC is the PRC Administrative Regulations on Foreign Exchange (《中華人民共和國外匯管理條例》) (the "**Foreign Exchange Regulations**"), which was promulgated by the State Council on January 29, 1996 and most recently revised on August 5, 2008. According to the Foreign Exchange Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign 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 (外匯管理局) (the "**SAFE**") or its local counterpart and other relevant PRC governmental authorities.

According to the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested 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》) (the "**Circular 19**"), which was promulgated by the SAFE on March 30, 2015, came into effect on June 1, 2015 and revised on December 30, 2019, a foreign-invested enterprise may, according to its actual business needs, settle with a bank the portion of the foreign exchange capital in its capital account, i.e., a bank account opened by a foreign-invested enterprise where the foreign shareholder(s) are required to remit and deposit the amount of respective capital contributions, for which the relevant foreign exchange bureau has confirmed monetary contribution rights and interests (or for which the bank has registered the account-crediting of monetary contribution). Meanwhile, the use of such RMB should still comply with the restrictions set in the Circular 19 that it cannot be directly or indirectly used for making payments beyond the business scope of the enterprise or payments prohibited by national laws and regulations, investing in securities unless otherwise provided by laws and regulations, granting the entrust loans in RMB (unless permitted by the scope of business), repaying the inter-enterprise borrowings (including advances by the third party) repaying the bank loans in RMB that have been lent to a third party, and paying the expenses related to the purchase of real estate not for self-use, except for the foreign-invested real estate enterprises.

The Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the "**FDI Provisions**"), which were promulgated by the SAFE on May 10, 2013 and amended on October 10, 2018, regulate and clarify the administration over foreign exchange administration in foreign direct investments. On December 30, 2019, the SAFE repealed the provision about annual inspection for foreign-invested enterprises in appendix 1 and all provisions in appendix 3 of the FDI

Provisions by issuing Notice of the SAFE on Repealing and Invalidating 5 Regulatory Documents on Foreign Exchange Administration and the Clauses of 7 Regulatory Documents on Foreign Exchange Administration (《國家外匯管理局關於廢止和失效5件外匯管理規範性文件及7件外匯管理規範性文件條款的通知》).

On June 9, 2016, the SAFE promulgated the Notice on Reforming and Standardizing the Administrative Provisions on Capital Account Foreign Exchange Settlement (《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》) (the "**Circular 16**"). According to the Circular 16, enterprises registered in China could settle the external debts in foreign currencies to RMB at their own discretion. The SAFE Circular 16 sets a uniform standard for discretionary settlement of foreign currencies under capital accounts (including but not limited to foreign currency capital and external debts), which is applicable to all enterprises registered in China. It reiterated that the RMB funds obtained from the settlement of foreign currencies shall not be used directly or indirectly for purposes beyond the company's scope of business, and shall not be used for domestic securities investment or investments and wealth management products other than principal-protected products issued by banks, unless otherwise expressly prescribed. Furthermore, such RMB funds shall not be used for disbursing loans to non-affiliated enterprises, unless the scope of business expressly provides so; and shall not be used to construct or purchase real estate not for self-use (except for real estate enterprises).

Circular 37

The Circular on Related Issues concerning Foreign Exchange Administration for Domestic Residents to Engage in Overseas Investment and Financing and in Round-trip Investment via Special Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the "**Circular 37**") was promulgated by the SAFE on July 4, 2014. Under Circular 37, PRC residents, individuals or institutions are required to register with the bureau of foreign exchange administration before they invest in a special purpose vehicle (the "**SPV**") with legitimate assets or equity interests inside and outside the PRC. In addition, any PRC resident that is a shareholder of an offshore SPV is required to amend its SAFE registration in a timely manner after any major changes of the offshore SPV being made, such as any increase or decrease of capital, stock right assignment or exchange, or merger or division, or any alteration in the basic information, such as name and operating duration of the individual domestic resident shareholder. Failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions being imposed on the subsequent foreign exchange activities of the relevant PRC residents, including the remitting back of dividends and profits. PRC residents who invest in an SPV with legitimate assets or equity interests inside and outside the PRC prior to the implementation of the Circular 37, but fail to conduct the foreign exchange registration of overseas investments, must submit an explanatory statement and state the reasons for doing so to the SAFE. The SAFE may allow complementary registration under the principles of legality and legitimacy. In the event of any violation of foreign exchange regulations by the PRC resident that applies for complementary registration, administrative penalties could be imposed in accordance with relevant laws.

According to the Circular on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》), which was promulgated by the SAFE on February 13, 2015, came into effect on June 1, 2015, and revised on December 30, 2019, registrations under Circular 37 will be handled directly by the bank that has obtained the financial institution identification codes issued by the foreign exchange regulatory authorities and that has opened the capital account information system at the local foreign exchange regulatory authority. Foreign exchange regulatory authorities will perform indirect regulation over the direct investment-related foreign exchange registration via the banks.

Dividend Distribution

On January 26, 2017, the SAFE promulgated the Notice on Improving the Verification of Authenticity and Compliance to Further Promote Foreign Exchange Control (《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 stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Other Regulations in relation to Our Business

Enterprise Income Tax

According to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得税法》) (the "**EIT Law**"), which was promulgated by the Standing Committee of the National People's Congress on March 16, 2007 and most recently amended on December 29, 2018, the income tax for both domestic and foreign-invested enterprises is at a uniform rate of 25% and the income tax for non-resident enterprise is at the rate of 20%. The Regulation on the Implementation of Enterprise Income Tax Law (《中華人民共和國企業所得税法實施條例》) (the "**EIT Rules**") was promulgated by the State Council on December 6, 2007 and amended on April 23, 2019. Pursuant to the EIT Law and the EIT Rules, a PRC resident enterprise is subject to enterprise income tax for the income derived from both inside and outside the PRC. A non-resident enterprise having offices or establishments inside the PRC is subject to enterprise income tax for the income derived in the PRC and the income derived from outside the PRC but with actual connection with such offices or establishments in the PRC. A non-resident enterprise without offices or establishments in the PRC or a non-resident enterprise whose earning income is not connected with its offices or establishments in the PRC will only be subject to tax on its PRC-sourced income. The income for such enterprise will be taxed at the reduced rate of 10%.

Pursuant to the EIT Law and the EIT Rules, income from equity investment between qualified resident enterprises such as dividends and bonuses, which refers to investment income derived by a resident enterprise from direct investment in another resident enterprise, is tax-exempt income. Moreover, the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Incomes (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》) was promulgated by the State Taxation Administration (the "**SAT**") on August 21, 2006 and was most recently amended by the Fifth Protocol ratified by the SAT on July 19, 2019 and came into effect on December 6, 2019. The Arrangement stipulates that a PRC resident enterprise which distributes dividends to its Hong Kong shareholders should pay income tax according to PRC law; however, if the beneficiary of the dividends is a Hong Kong resident enterprise, which directly holds no less than 25% equity interests of the aforementioned enterprise (i.e. the dividend distributor), the tax levied shall be 5% of the distributed dividends. If the beneficiary is a Hong Kong resident enterprise, which directly holds less than 25% equity interests of the aforementioned enterprise, the tax levied shall be 10% of the distributed dividends. Meanwhile, the Announcement of the State Administration of Taxation on Certain Issues Concerning the "Beneficial Owners" in the Tax Treaties (《國家税務總局關於税收協定中"受益所有人"有關問題的公告》), promulgated by the SAT on February 3, 2018 and came into effect on April 1, 2018, has stipulated some factors that are unfavorable to the determination of "beneficial owner."

In addition, under the Circular of the SAT on Relevant Issues Concerning the Implementation of Dividend Clauses in Tax Treaties (《國家税務總局關於執行税收協定股息條款有關問題的通知》), which was promulgated by the SAT and came into effect on February 20, 2009, all of the following requirements should be satisfied where a tax resident of the counterparty to the tax treaty needs to be entitled to such tax treatment specified in the tax treaty for the dividends paid to it by a PRC resident enterprise: (i) such tax resident who obtains dividends should be a company as provided in the tax treaty; (ii) the equity interests and voting shares of the PRC resident enterprise directly owned by such a tax resident reach a specified percentage; and (iii) the capital ratio of the PRC resident enterprise directly owned by such a tax resident reaches the percentage specified in the tax treaty at any time within 12 consecutive months prior to acquiring the dividends.

Regulations on PRC enterprise income tax on indirect transfer of non-resident enterprises

On February 3, 2015, the SAT issued the Announcement of the State Administration of Taxation on Certain Issues Concerning the Enterprise Income Tax on the Indirect Transfer of Properties by Non-resident Enterprises (《關於非居民企業間接轉讓財產企業所得税若干問題的公告》) (the "**Circular 7**"), which was last amended on December 29, 2017. Circular 7 stipulates that when a non-resident enterprise transfers the assets (including equity interests) in an overseas holding company which directly or indirectly owns PRC taxable properties, including shares in a PRC company (or PRC Taxable Assets), for the purposes of avoiding PRC enterprise income taxes through an arrangement without reasonable commercial purpose, such indirect transfer should be reclassified and recognized to be a direct transfer of the assets

(including equity interests) of a PRC resident enterprise in accordance with the Enterprise Income Tax Law, unless the overall arrangements relating to an indirect transfer of PRC Taxable Assets fulfil one of the conditions as stipulated under the Circular 7.

Further, according to the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises (《關於非居民企業所得稅源泉扣繳有關問題的公告》) issued by the SAT on October 17, 2017 and revised on June 15, 2018, the "income from property transfer" shall include the income from the transfer of equity interests and equity investment assets (hereinafter referred to as "equities"). The balance after deducting the net value of equities from the income from equity transfer is the taxable income from equity transfer. When calculating the income from equity transfer, an enterprise shall not deduct the amount that may be distributed from the shareholders' retained proceeds that are attributable to such equities, such as the undistributed profits of the invested enterprise.

Environmental Protection

The PRC Environmental Protection Law (《中華人民共和國環境保護法》) (the "**Environmental Protection Law**"), which was promulgated by the Standing Committee of the National People's Congress on December 26, 1989, amended on April 24, 2014 and came into effect on January 1, 2015, provides a regulatory framework to protect and develop the environment, prevent and reduce pollution and other public hazards, and safeguard human health. The environmental protection department of the State Council is in charge of promulgating national standards for environmental protection. The Environmental Protection Law requires any facility that produces pollutants or other hazards to adopt environmental protection measures in its operations and establish an environmental protection responsibility system. Enterprises that are in violation of the Environmental Protection Law may be subject to a warning, payment of damages, imposition of a fine, or limitation or suspension of production depending on the seriousness of the case. If a criminal offense is committed, the offender may be subject to criminal penalties.

According to the PRC Law on Environment Impact Assessment (《中華人民共和國環境影響評價法》) promulgated by the Standing Committee of the National People's Congress on October 28, 2002 and most recently amended on December 29, 2018, the Administrative Regulations on the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998 and amended on July 16, 2017, the Interim Measures for the Environmental Protection Acceptance upon the Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated on November 20, 2017 and other relevant environmental laws and regulations, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work. Upon completion of a construction project, the construction unit shall

prepare an acceptance check report and make it available to the public. The principal part of a construction project may be put into production or use only after the affiliated environmental protection facilities have passed the acceptance check.

According to the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into effect on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated on January 22, 2015 and came into effect on March 1, 2015, enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for collecting the permit for discharging sewage into drainage pipelines. Drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the state. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

Regulations on Fire Protection

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the "**Fire Prevention Law**"), which was promulgated on April 29, 1998 and most recently amended on April 29, 2021, provides that fire control design and construction of a construction project shall comply with the State's fire control technical standards for construction projects. Developers, designers, builders, project supervisors, etc. shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. The development project fire safety design examination and acceptance system shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards for project construction.

According to the Eight Measures for the Public Security and Firefighting Departments to Deepen Reform and Serve Economic and Social Development promulgated by the Ministry of Public Security of the PRC (《公安消防部門深化改革服務經濟社會發展八項措施》) on August 12, 2015, the fire protection design and completion acceptance fire protection record of construction projects with an investment of less than RMB300,000 or a building area of less than 300 square meters (or below the limit determined by the housing and urban construction department of the provincial people's government) was cancelled.

Employee Stock Option Plans

On February 15, 2012, the SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《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》) (the "**Share Option Rules**"). Under the Share Option Rules, the PRC citizens or residents habitually residing in the PRC continuously for over one year, with a few

exceptions, and who have been granted, restricted shares or share options by an overseas listed company according to its employee share option or share incentive plan, are required to appoint a qualified PRC agent, register with the SAFE or its local counterparts and complete certain other procedures related to the shareholding plan, share option plan or other similar share incentive plans. Concurrent with registration with the SAFE or its local counterparts, the qualified PRC agent is required to obtain an approval from the SAFE for an annual allowance for the foreign exchanges in connection with shareholding or the exercise of a share option, and an approval for opening a special foreign exchange account at a PRC domestic bank to hold the funds required in connection with share purchases or share option exercises, returned principals or profits upon sale of shares, dividends issued on the stock and any other income or expenditures approved by the SAFE. Currently, foreign exchange income of the participating PRC residents received from the sale of share and dividends distributed by the overseas listed company are required to be fully remitted into such special domestic foreign currency account before distribution to such participants. In addition, the PRC agents are required to amend or deregister the registrations with the SAFE or its local counterparts in case of any material change in, or termination of, the share incentive plans within the time periods provided by the Share Option Rules.

Labor and Social Insurance

The PRC Labor Law (《中華人民共和國勞動法》) which was promulgated by the Standing Committee of the National People's Congress on July 5, 1994 and most recently amended and took effect on December 29, 2018, and the PRC Labor Contract Law (《中華人民共和國勞動合同法》) which was promulgated by the Standing Committee of the National People's Congress on June 29, 2007 and amended on December 28, 2012 and took effect on July 1, 2013, govern the relationship between employers and employees and provides for specific provisions in relation to the terms and conditions of an employment contract. The PRC Labor Contract Law stipulates that employment contracts must be in writing and signed. It imposes more stringent requirements on employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

Under applicable PRC laws and regulations, including the PRC Social Insurance Law (《中華人民共和國社會保險法》), which was promulgated by the Standing Committee of the National People's Congress on October 28, 2010 and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and latest amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999, and most recently amended on March 24, 2019, employers and/or employees (as the case may be) are required to contribute to a number of social security funds, including funds for basic pension insurance, employment insurance, basic medical insurance, occupational injury insurance, maternity insurance, and housing provident funds. These payments are made to local administrative authorities and employers who fail to contribute may be fined and ordered to rectify within a stipulated time limit.

Regulations in Relation to Overseas Listing

On December 24, 2021, the CSRC released the Administrative Provisions of the State Council on the Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草案徵求意見稿)》) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (collectively the "**Draft Regulations on Overseas Listing**") for public comments until January 23, 2022.

The Draft Regulations on Overseas Listing, if adopted in their current form, will regulate both direct and indirect overseas offering and listing of PRC domestic companies by adopting a filing-based regulatory regime. Pursuant to the Draft Regulations on Overseas Listing, the issuers who meet the following criteria seeking to offer their securities or list overseas will be deemed as indirect overseas offering by PRC domestic companies: (a) whose PRC domestic operating entity generated more than 50% of the total assets, net assets, revenues or profits as shown in the issuer's audited consolidated financial statements in the most recent accounting year, and (b) whose senior management in charge of business operation and management are mostly Chinese citizens or have domicile in China, and whose main places of business are located in China or main business activities are conducted in China. PRC domestic companies that directly or indirectly seek to offer or list their securities overseas are required to file with the CSRC within 3 working days after submitting their application documents to the regulator in the place of intended listing or offering. In addition, according to the Draft Regulations on Overseas Listing, overseas offerings and listings (i) that are prohibited by specific laws and regulations, (ii) that constitute threat to or endanger national security as reviewed and determined by competent authorities, (iii) that involve material ownership disputes, (iv) where the PRC domestic companies, their controlling shareholder or actual controller are convicted of or investigated for certain criminal offences, or directors, supervisors and senior management of the issuer involved in certain criminal offences or severe administrative penalties (together the "**Forbidden Circumstances**"), among other circumstances, are explicitly forbidden.

As of the Latest Practicable Date, the Draft Regulations on Overseas Listing were released for public comments only and the final version and effective date of such regulations are subject to substantial uncertainties. Therefore, the [**REDACTED**] is currently not subject to any filing procedures with, or approval from, the CSRC. As of the Latest Practicable Date, we had not received any inquiries, notices, warnings, or sanctions regarding the [**REDACTED**] from the CSRC or any other PRC government authorities in terms of compliance with the proposed filing requirement under the new regulatory regime, if enacted. To our Directors' best knowledge, we are not aware of the existence of any circumstances that would prohibit us from conducting overseas offering and listings under the Draft Regulations on Overseas Listing. Therefore, if the Draft Regulations on Overseas Listing become effective in their current form before the [**REDACTED**] is completed, other than the uncertainties of the filing procedures which may be further clarified in the final version of the Draft Regulations on Overseas Listing and/or their implementation rules, we do not foresee any impediment for us to comply with the Draft Regulations on Overseas Listing in any material respects.

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.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (the "PHSA") and their 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 and the subsequent compliance with appropriate federal, state, and local 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 actions or judicial sanctions. 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 agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the pre-clinical 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. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

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 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 (the "IRB"), 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 for FDA 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 if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I 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 II 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 PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase III 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. 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 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**.

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 cGMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, pre-clinical 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 an NDA or BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA 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/BLA, 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/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA 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/BLA 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 either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or 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 IV 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.

In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Expedited Development and Review Programs

Accelerated Approval

Under 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 trial to confirm the effect on the clinical endpoint. Failure to conduct 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 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 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 product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical 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 U.S. 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 circumstance.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse 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 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. 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 pre-clinical 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 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.

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.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in 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 include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- 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 the "ACA") became law in the United States March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA, among other things, 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 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, President 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, for example, the Tax Act enacted

by the Congress in 2017 which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurance tax. There may be other efforts to challenge, repeal or replace the ACA. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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 an NDA or a 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 NDA/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 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 an NDA or a BLA has not been submitted.