Our businesses and operations in China are supervised and governed by Chinese regulatory authorities. This section primarily sets forth a summary of the principal PRC laws, rules and regulations relevant to our businesses and operations in China.

REGULATIONS RELATING TO REFORM AND CATEGORIES OF MEDICAL INSTITUTIONS

Pursuant to the Law of the People's Republic of China on the Promotion of Basic Medical Care, Hygiene and Health (《中華人民共和國基本醫療衛生與健康促進法》) which was promulgated by the Standing Committee of the National People's Congress, or SCNPC, and became effective on June 1, 2020, the PRC government encourages and guides social forces to legally establish and operate medical and health institutions to provide basic medical services.

The Guiding Opinions of the General Office of the State Council on Boosting the Construction of a Tiered Diagnosis and Treatment System (《國務院辦公廳關於推進分級診療制度建設的指導意見》), promulgated by General Office of the State Council and effective from September 8, 2015, signify the establishment of a tiered diagnosis and treatment system, as an important measure for rationally allocating medical resources and promoting equal access to basic medical and health services. The State Council requires the local governments to facilitate the establishment of independent regional medical testing institutions.

The Circular on Further Reforming and Perfecting the Examination and Approval of Medical Institutions and Doctors (《關於進一步改革完善醫療機構、醫師審批工作的通知》), which was jointly promulgated by the National Health Commission, or NHC, and the State Administration of Traditional Chinese Medicine and became effective on June 15, 2018, stipulates that medical institutions may, on the premise of ensuring medical quality and safety, entrust independent medical test laboratories to provide medical testing services.

REGULATIONS RELATING TO LABORATORIES

Medical Test Laboratories

Pursuant to the Administrative Regulations on Medical Institutions (《醫療機構管理條例》), promulgated by the State Council, effective on September 1, 1994, and latest amended on March 29, 2022, and the Implementation Measures of the Administrative Regulations on Medical Institutions (《醫療機構管理條例實施細則》), effective on September 1, 1994, latest amended by National Health and Family Planning Commission, or NHFPC, the former of NHC, and effective from April 1, 2017, the establishment of a medical institution, including but not limited to medical test laboratory, shall comply with the setting up plan and basic standards for medical institutions, and shall apply for an approval from NHC or its local counterparts to obtain a medical institution practicing license. The Administrative Measures for the Examination of Medical Institutions (for Trial Implementation) (《醫療機構校驗管理辦法(試行)》), which were promulgated by the Ministry of Health, or MOH, the former of NHFPC, and became effective on June 15, 2009, stipulate that a medical institution's practicing license is subject to periodic examinations and verifications by the registration authorities, and will be canceled if such medical institution fails to pass the examination.

Pursuant to the Basic Standards and Practice of Medical Test Laboratories (for Trial Implementation) (《醫學檢驗實驗室基本標準和管理規範(試行)》), promulgated by NHFPC and effective from July 20, 2016, a medical test laboratory, which conducts clinical tests, including clinical hematology tests and body fluid tests, clinical chemistry tests, clinical immunology tests, clinical microbiology tests, clinical molecular cytogenetic tests and clinical pathology tests, for the purpose of diagnosis, management, prevention or treatment of diseases and health assessment, shall be regulated as a medical institution and obtain a medical institution practicing license.

According to the Measures for the Administration of Clinical Laboratories of Medical Institutions (《醫療機構臨床實驗室管理辦法》) released by MOH, effective from June 1, 2006 and amended on July 10, 2020, a medical institution shall set up its clinical testing items according to its approved and registered professional diagnosis and treatment subjects under the health administrative department, and shall not carry out clinical testing items beyond the registered professional scope. Medical institutions shall in principle comply with the Catalogue of Clinical Testing Items for Medical Institutions (2013) (《醫療機構臨床檢驗項目目錄(2013年版)》), or the Testing Items Catalogue, promulgated by NHFPC on August 5, 2013. In addition, pursuant to the Notice on Issues Related to the Management of Clinical Laboratory Items (《關於臨床檢驗項目管理有關問題的通知》), promulgated by NHFPC on February 25, 2016, the clinical testing items which are not included in the Testing Items Catalogue, but with clear clinical significance, relatively high specificity and sensitivity, and reasonable price, shall be validated in time to meet clinical needs.

During the COVID-19 epidemic prevention and control period, independent medical test laboratories have been playing an active role in nucleic acid detection. Pursuant to the Notice of the General Office of the National Health Commission on Requirements for Medical Institutions to Carry out COVID-19 related Testing (《國家衛生健康委辦公廳關於醫療機構開展新型冠狀病毒核酸檢測有關要求的通知》), or the COVID-19 Notice, issued by the General Office of the NHC on January 22, 2020, each province can procure COVID-19 related testing services and cooperate with qualified third-party testing institutions to carry out testing. The COVID-19 Notice further provided various testing requirements on COVID-19 related testing to regulate testing procedure, including sample collection, sample storage and transportation, quality control, etc. To further strengthen the management on independent medical test laboratories and ensure medical quality and safety, the medical treatment team under the Joint Prevention and Control Mechanism of the State Council has formulated and issued the Interim Administrative Measures for Medical Test Laboratories (《醫學檢驗實驗室管理暫行辦法》), which became effective from August 1, 2020, on the basis of the Practice of Medical Test Laboratories (for Trial Implementation) (《醫學檢驗實驗室管理規範(試行)》). Meanwhile, the laboratories shall strictly comply with the Measures for the Administration of Clinical Laboratories of Medical Institutions (《醫療機構臨床實驗室管理辦法》), and shall participate in the medical test external quality assessment activities at or above the provincial level, so as to ensure the impartiality and accuracy of testing results.

Clinical Gene Amplification Test Laboratories

Pursuant to the Administrative Measures for Clinical Gene Amplification Test Laboratories of Medical Institutions (《醫療機構臨床基因擴增檢驗實驗室管理辦法》), promulgated by MOH and effective from December 6, 2010, a medical institution that intends to establish a clinical gene amplification laboratory shall file an application with the NHC at the provincial level, and register its clinical testing items with the competent NHC after technical verification passed by the clinical testing center at the provincial level or institution designated by the NHC at the provincial level.

Pathogenic Microorganism Laboratories

Pursuant to the Regulations on Administration of Bio-safety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), promulgated by the State Council, effective on November 12, 2004, and latest amended on March 19, 2018, pathogenic microorganism laboratories are classified into four levels, namely bio-safety levels 1, 2, 3 and 4 in terms of bio-safety protection levels in accordance with national standards on biosafety of laboratories. Laboratories at bio-safety levels 1 and 2 shall not engage in laboratory activities related to highly pathogenic microorganisms. The construction, alteration or expansion of a laboratory at bio-safety level 1 or 2 shall be filed for record with the local counterparts of NHC. The entity launched a pathogenic microorganism laboratory shall develop a scientific and strict management system, regularly inspect the implementation of the regulations on bio-safety, and regularly inspect, maintain and update the facilities, equipment and materials in the laboratory, to ensure its compliance with the national standards.

REGULATIONS RELATING TO MEDICAL TECHNOLOGIES

Pursuant to the Administration Measures for the Clinical Application of Medical Technologies (《醫療技術臨床應用管理辦法》) promulgated by NHC on August 13, 2018 and effective from November 1, 2018, a negative list will be set up regarding the clinical application of medical technologies, which are classified into two categories: "restricted" and "prohibited". Any medical institution shall refrain from conducting any clinical application of medical technologies that fall within the "prohibited" category, while a medical institution which engages in clinical application of medical technologies falling within the "restricted" category shall file with MOH or its local counterpart within fifteen working days after the first clinical application of such technologies. In addition, pursuant to the Notice of Strengthening the Administration of Products and Technologies Relating to Clinical Gene Sequencing (《關於加強臨床使用基因測序相關產品和技術管理的通知》), jointly promulgated by General Office of NHFPC and China Food and Drug Administration, or CFDA, the former of the National Medical Products Administration, or NMPA, on February 9, 2014, no medical institutions may apply gene sequencing technologies or products for clinical use before the issuance of relevant access standards and management regulations.

REGULATIONS RELATING TO MEDICAL DEVICES

The using and operation of medical devices in China are subject to extensive regulations.

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), or the Medical Devices Regulation, promulgated by the State Council and effective from April 1, 2000, latest amended on February 9, 2021 and came into effect on June 1, 2021, and the Administrative Measures of Registration and Filing of In-vitro Diagnostic Reagents (《體外診斷試劑注冊與備案管理辦法》), promulgated by SAMR and effective from October 1, 2021, medical devices, including in-vitro diagnostic reagents, are classified into three different categories, Class I, II and III on the basis of their respective degrees of risk. Medical devices of Class I refer to such devices with low level of risk, the safety and effectiveness of which can be ensured through routine administration. Medical devices of Class II refer to such devices with medium level of risk, the safety and effectiveness of which shall be strictly controlled. Medical devices of Class III refer to such devices with high level of risk, the safety and effectiveness of which shall be guaranteed and be subject to strict control through special administrative measures. The Notice of Strengthening the Administration of Products and Technologies Relating to Clinical Gene Sequencing (《關於加強臨床使用基因測序相關產品和技術管理的通知》), jointly promulgated by CFDA and NHFPC, and effective from February 9, 2014, further provides that gene sequencing diagnostic products, including gene sequencers and relevant diagnostic reagents and software, shall be regulated as medical devices.

Registration and Filing of Medical Devices

Pursuant to the Medical Devices Regulation, and the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) promulgated by the SAMR and took effect on October 1, 2021, medical devices of Class I are subject to record-filing, while medical devices of Class II and Class III are subject to registration. The Medical Devices Regulation also stipulates that qualified medical institutions may, under the circumstances that there have been no in-vitro diagnostic reagents of the same type marketed in the PRC, research and develop such products on their own initiatives according to their clinical needs, and use them within the institutions under the guidance of practicing physicians.

According to the Medical Devices Regulation, when the operating enterprises of medical devices or users purchase medical devices, they shall check the qualification of suppliers and the eligible supporting materials of medical devices, and establish relevant entry inspection record system. The operating enterprises engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices shall establish a sales record system.

Operation Permit and GSP for Medical Devices

Pursuant to the Medical Devices Regulation and the Administrative Measures for Operation of Medical Devices (《醫療器械經營監督管理辦法》), or the Medical Devices Operation Measures, promulgated by CFDA, and latest amended on March 10, 2022 and effective from May 1, 2022, an entity engaging in the operation of medical devices of Class I is not required to obtain approval or filing for record with NMPA, or its local counterparts; an entity engaging in the operation of medical devices of Class II shall file for record with NMPA at city level where such entity is located; an entity engaging in the operation of medical devices of Class III shall apply for an operation permit from NMPA at city level. The operation permit of medical devices is valid for five years and the holder of such permit shall apply for extension within 30 to 90 working days prior to its expiration. According to the Medical Devices Regulation, any entity shall not sell or use medical devices which are not properly registered or filed with NMPA or its local counterparts. In addition, according to the Medical Devices Operation Measures, no additional operation permit or filing is required for any registered holder or record holder of medical devices or manufacturer of medical devices if it sells the medical devices at the place where it is domiciled or where the medical devices are manufactured.

Pursuant to the Good Sales Practice of Medical Devices (《醫療器械經營質量管理規範》) promulgated by CFDA and effective from December 12, 2014, an entity engaging in the procurement, acceptance, preservation, sales, transportation and after-sales of medical devices shall take effective quality control measures so as to ensure the quality and safety of products in the process of business operations.

Importation of Medical Devices

According to the Medical Devices Regulation, imported medical devices shall be registered or filed with NMPA or its local counterparts in accordance with the provisions of the Medical Devices Regulation. Imported medical devices shall have instructions and labels in Chinese.

REGULATIONS RELATING TO IMPORTED AND EXPORTED GOODS

Pursuant to the Administrative Provisions of the Customs of the People's Republic of China on the Filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》) promulgated by the General Administration of Customs of China, or GACC, on November 19, 2021 and took effect on January 1, 2022 and the Administrative Provisions of the Customs of the People's Republic of China on the Declaration of Imported and Exported Goods (《中華人民共和國海關進出口貨物申報管理規定》) promulgated by GACC on September 18, 2003 and newly revised on November 23, 2018, consignors and consignees of exported and imported goods shall declare to the customs by themselves or appoint a customs declaration enterprise to declare to the customs on their behalf, and shall go through customs declaration entity filing formalities with their local customs in accordance with the applicable provisions. Consignors and consignees of exported and imported goods may handle their own customs declarations within the customs territory of the PRC.

REGULATIONS RELATING TO PRODUCT QUALITY

The Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》), as amended and effective as of December 29, 2018, applies to production and sale activities in the PRC. Pursuant to the Product Quality Law of the People's Republic of China, products offered for sale must satisfy relevant quality and safety standards. Violations of state or industrial standards for health and safety and any other related violations may result in civil liabilities and administrative penalties, such as compensation for damages, fines, suspension or shutdown of business, as well as confiscation of products illegally produced and sold and the proceeds from such sales. Severe violations may subject the responsible individual or enterprise to criminal liabilities. Where a defective product causes physical injury to a person or damage to another person's property, the victim may claim compensation from the manufacturer or from the seller of the product. Where the responsibility for product defects lies with the manufacturer, the seller shall, after settling compensation, have the right to recover such compensation from the manufacturer, and vice versa.

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) which was promulgated on May 5, 2020 and effective from January 1, 2021, 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.

REGULATIONS RELATING TO HUMAN GENETIC RESOURCES

The Regulation for the Administration of Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》), or the HGR Regulation, promulgated by the State Council on May 28, 2019, and effective from July 1, 2019, regulates entities engaging in collection, preservation, utilization and outbound provision of human genetic resources. Human genetic resources include (i) human genetic resources materials, such as organs, tissues and cells that contain hereditary substances such as human genomes genes, and (ii) human genetic resources information, such as data generated from human genetic resources.

Pursuant to the HGR Regulation, collection and preservation of human substances such as organs, tissues and cells and carrying out related activities for the purposes of clinical diagnosis and treatment, blood collection and supply services, crime investigation, doping detection and funeral and interment shall be subject to other applicable laws and administrative regulations.

Pursuant to the HGR Regulation, foreign entities, individuals and such entities established or actually controlled thereby shall not, within the territory of China, collect or preserve human genetic resources of China, nor provide human genetic resources of China outward across the border; while a foreign entity is allowed to conduct scientific research activities by utilizing human genetic resources of China through cooperation with scientific research institutions, higher education institutions, medical institutions or enterprises of China. The utilization of human genetic resources of China in any international cooperative scientific research is subject to approval by the Ministry of Science and Technology, or MOST. However, the aforesaid approval is not required, but instead a filing for record with MOST is required, if human genetic resources of China are utilized for international cooperative clinical trials without any outbound provision of human genetic resources, for the purpose of obtaining product registration of relevant medicine and medical device in China.

REGULATIONS RELATING TO PRICE OF HEALTHCARE SERVICES

According to the Notice of Issues Related to the Implementation of Market Price Adjustment by Non-Public Medical Institutions (《關於非公立醫療機構醫療服務實行市場調節價有關問題的通知》) promulgated and implemented on March 25, 2014 by the National Development and Reform Commission of the PRC, or NDRC, the NHFPC and the Ministry of Human Resources and Social Security, or MOHRSS, prices on healthcare services provided by non-public medical institutions shall be set with reference to the market level.

In addition, the Circular on the Issuance of the Reform of the Pharmaceutical and Healthcare Services Price Formulation Mechanism (《關於印發改革藥品和醫療服務價格形成機制的意見的通知》) was jointly promulgated by NDRC, NHFPC and MOHRSS, and came into effect on 9 November 2009. It provides that both the government-directed price and market-based price shall apply to the provision of healthcare services: price for basic healthcare services provided by non-profit medical institutions shall be directed by government-directed pricing guidelines, while price for healthcare services provided by profitable medical institutions and certain special categories of healthcare services provided by non-profit medical institutions can be determined by the market.

REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

Pursuant to the Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》) which was promulgated by SCNPC on December 26, 1989, and amended on April 24, 2014 and came into force on January 1, 2015, all enterprises and institutions which discharge pollutants shall adopt measures to prevent and control pollution and damage to the environment from waste gas, waste water, waste residues, medical waste, dust, malodorous gases, radioactive substances, noise, vibration, ray radiation and electromagnetic radiation generated in the course of production, construction or other activities. Pollution prevention and control facilities of a construction project shall be simultaneously designed, constructed and put into operation with the principal part of the construction project. Enterprises that manufacture, store, transport, sell, use or dispose of chemicals and materials containing radioactive substances shall comply with the relevant State regulations to prevent environmental pollution. The relevant authorities are authorized to impose various types of penalties on the persons or entities in violation of the environmental regulations, including fines, restriction or suspension of operation, shut-down, detention of office-in-charge, etc.

Pursuant to the Environmental Impact Assessment Law of the People's Republic of China (《中華人民共和國環境影響評價法》) promulgated by SCNPC on October 28, 2002, effective on September 1, 2003 and latest amended on December 29, 2018, the PRC government implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report or an environmental impact form or complete an environmental impact registration form (the "Environmental Impact Assessment Documents") for reporting and filing purposes. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

Pursuant to the Administrative Regulations on Environmental Protection in Construction Projects (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998, amended and effective on October 1, 2017 and the Interim Measures on Administration of Environmental Protection for Acceptance Examination Upon Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated by the former Ministry of Environmental Protection on 20 November 2017, where a construction project needs complementary environmental protection facilities, those facilities must be designed, constructed and become operational at the same time as the main parts of the project. The project owner shall, after the completion of the construction project for which the environmental impact report or the environmental impact statement is prepared, according to standards and procedures prescribed by the environmental protection administrative department of the State Council, conduct acceptance check of the constructed complementary environmental protection facilities. The construction project may not be put into production or use until the constructed supporting environmental protection facilities have passed the acceptance check. The facilities that have not undergone or fail to pass the acceptance check shall not be put into production or use.

According to the Regulations on the Management of Medical Waste (《醫療廢物管理條例》), which were promulgated by the State Council on June 16, 2003 and amended on January 8, 2011, and the Implementation Measures of the Management of Medical Waste (《醫療衛生機構醫療廢物管理辦法》), which were promulgated by MOH on October 15, 2003 and came into effect on the same day, medical institution shall timely deliver medical wastes to an entity for centralized disposal of medical wastes and licensed by a relevant environment protection administrative department for dispose. Sewage generated by any medical institution and excretion of its patients or suspected patients of infectious diseases shall be sterilized in strict accordance with the relevant provisions, and shall not be discharged into sewage disposal systems until the relevant standards are met.

REGULATIONS RELATING TO LABOR PROTECTION

Labor Protection

Pursuant to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), promulgated by SCNPC on July 5, 1994 and amended and effective on December 29, 2018 and the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》) amended by SCNPC and effective on July 1, 2013 and the Implementation Rules of the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council and effective on September 18, 2008, employers shall establish and improve labor rules and regulations according to the laws and regulations and shall strictly comply with the national standards, provide trainings to their employees, protect their labor rights and perform its labor obligations. Employers shall execute written labor contracts with full-time employees. Labor contracts shall be categorized into labor contracts with fixed term, labor contracts without fixed term and labor contracts to be expired upon completion of certain tasks. All employers must comply with local minimum wage standards.

Social Insurance and Housing Provident Fund

In addition, according to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》) promulgated by SCNPC on October 28, 2010, amended and came into effect on December 29, 2018 and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》) amended by the State Council and came into effect on March 24, 2019 and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) amended by the State Council and came into effect on March 24, 2019, employers in the PRC shall pay premium for basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, basic medical insurance and housing provident funds for its employees at the applicable rates based on the amounts stipulated by the laws.

REGULATIONS RELATING TO FOREIGN INVESTMENT

On March 15, 2019, the National People's Congress promulgated the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》), or the 2019 Foreign Investment Law, which became effective on January 1, 2020 and replaced the major former laws and regulations governing foreign investment in the PRC. Pursuant to the 2019 Foreign Investment Law, "foreign investments" refer to investment activities conducted by foreign investors directly or indirectly in the PRC, which include any of the following circumstances: (i) foreign investors setting up foreign-invested enterprises in the PRC solely or jointly with other investors, (ii) foreign investors obtaining shares, equity interests, property portions or other similar rights and interests of enterprises within the PRC, (iii) foreign investors investing in new projects in the PRC solely or jointly with other investors, and (iv) investment of other methods as specified in laws, administrative regulations, or as stipulated by the PRC State Council. The 2019 Foreign Investment Law does not comment on the concept of "de facto control" or contractual arrangements with consolidated affiliated entities, however, it has a catch-all provision under definition of "foreign investment" to include investments made by foreign investors in China through means stipulated by laws or administrative regulations or other methods prescribed by the State Council. Therefore, it still leaves leeway for future laws, administrative regulations or provisions to provide for contractual arrangements as a form of foreign investment.

According to the 2019 Foreign Investment Law and its implementing rules, China adopts a system of pre-entry national treatment plus negative list with respect to foreign investment administration. The negative list will be proposed by the competent investment department of the State Council in conjunction with the competent commerce department of the State Council and other relevant departments, and be reported to the State Council for promulgation, or be promulgated by the competent investment department or competent commerce department of the State Council after being reported to the State Council for approval.

On December 30, 2019, MOFCOM and the State Administration for Market Regulation jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), or the Information Reporting Measures, which became effective on January 1, 2020. Pursuant to the Information Reporting Measures, where a foreign investor directly or indirectly carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment related information to the competent commerce authority through the enterprise registration system and the national enterprise credit information publicity system for further handling.

Foreign investment beyond the negative list will be granted national treatment. Foreign investors shall not invest in the prohibited industries as specified in the negative list, while foreign investment must satisfy certain conditions stipulated in the negative list for investment in the restricted industries. The current industry entry clearance requirements governing investment activities in the PRC by foreign investors are set out in two categories, namely the Special Administrative Measures on Access of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)》), the latest amended version of which was jointly promulgated by the Ministry of Commerce, or MOFCOM, and NDRC on December 27, 2021 and took effect as of January 1, 2022, or the 2021 Negative List, and the Encouraged Industry Catalogue for Foreign Investment (2022 version) (《鼓勵外商投資產業目錄(2022年版)》). Industries not listed in these two categories are generally deemed "permitted" for foreign investment unless otherwise restricted by other PRC laws. Development and application of gene diagnosis and treatment technology is prohibited to foreign investment pursuant to the 2021 Negative List. We conduct the business operations of clinical genetic testing service involving development and application of genetic diagnosis and treatment technologies that are prohibited to foreign investment, through Hangzhou Adicon and its subsidiaries under the Contractual Arrangements.

According to Article 6 of the 2021 Negative List, if a domestic company engaging in business prohibited in the Negative List seeks to offer shares and list securities in an overseas market, such offering and listing shall be approved by relevant competent PRC authorities. Foreign investors must not participate in the operation and management of the company, and their shareholding percentage shall be subject to relevant provisions on the administration of domestic securities investment by foreign investors. On January 18, 2022, the NDRC held a press conference to further clarify the 2021 Negative List, during which the spokesmen make it clear that Article 6 of the 2021 Negative List shall only be applicable where a domestic company is seeking a direct overseas issuance and listing. With reference to the definition under the Overseas Listing Trial Measures, a direct overseas issuance and listing of a domestic company refers to a PRC-incorporated joint stock company issues shares or seeks to be listed overseas, where the listed company is the domestic company itself, such as H shares listing (the "Direct Overseas Listing"). Our PRC Legal Advisor is of the view that based on the clarification made by the NDRC, our proposed [**REDACTED**] does not constitute a Direct Overseas Listing, which is a case applicable under the Article 6 of the 2021 Negative List.

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (境內企業境外發行證券和上市管理試行辦法) (the "**Overseas Listing Trial Measures**") and five supporting guidelines, which will come into effect on March 31, 2023. The Overseas Listing Trial Measures will regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime.

Pursuant to the Overseas Listing Trial Measures, if the issuer both meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer's business activities are conducted in the PRC, or its main place(s) of business are located in the PRC, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in the PRC. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also requires subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and listings.

On the same day, the CSRC also held a press conference for the release of the Overseas Listing Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (關於境內企業境外發行上市備案管理安排的通知), which, among others, clarifies that (1) the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing applicants (存量企業), or the Existing Applicants. Existing Applicants are not required to complete the filling procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved; (2) on or prior to the effective date of the Overseas Listing Trial Measures, domestic companies that have already submitted valid applications for overseas offering and listing but fail to obtain an approval from overseas regulatory authorities or stock exchanges may reasonably arrange the timing for submitting their filing applications with the CSRC, and must complete the filing before the completion of their overseas offering and listing; (3) a six-month transition period will be granted to domestic companies which, prior to the effective date of the Overseas Listing Trial Measures, have already obtained the approval from overseas regulatory authorities or stock exchanges (such as pass of hearing for listing in Hong Kong or the effectiveness of registration statement for listing in the U.S.), but have not completed the indirect overseas listing; if such domestic companies complete their overseas offering and listing within such six-month period (i.e., on or prior to September 30, 2023), they will be deemed as Existing Applicants. Within such six-month transition period, however, if such domestic companies need to reapply for offering and listing procedures to the overseas regulatory authority or securities exchanges (such as being required to go through a new hearing procedure with the Stock Exchange), or if they fail to complete their indirect overseas issuance and listing, such domestic companies shall complete the filling procedures with the CSRC before completion of the overseas offering and listing; and (4) the CSRC will solicit opinions from relevant regulatory authorities and complete the filing of the overseas listing of companies with contractual arrangements which duly meet the compliance requirements, and support the development and growth of these companies by enabling them to utilize two markets and two kinds of resources.

The Overseas Listing Trial Measures provide that, an overseas offering and listing is prohibited under any of the following circumstances: if (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

REGULATIONS RELATING TO INTELLECTUAL PROPERTY RIGHTS

Patent

Patents in the PRC are principally protected under the Patent Law of the People's Republic of China (《中華人民共和國專利法》), or the Patent Law, promulgated by SCNPC, latest amended on October 17, 2020 and took effect on June 1, 2021 and the Implementing Rules of the Patent Law of the People's Republic of China (《中華人民共和國專利法實施細則》), promulgated by the State Council and last amended on January 9, 2010 and effective from February 1, 2010. The Patent Law and its implementation rules provide for three types of patent: "invention", "utility model" and "design". The protection period is 20 years for invention patents, 10 years for utility model patents and 15 years for design patents, commencing from their respective application dates. The Chinese patent system adopts a "first come, first file" principle, which means that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first. To be patentable, invention or utility models must meet three criteria: novelty, inventiveness and practicability. Except under certain specific circumstances provided by law, any third-party user must obtain consent or a proper license from the patent owner to use the patent. Otherwise, the use of said patent constitutes an infringement of the patent rights, and shall pay compensation to the patentee and is subject to order to cease infringement. In addition, under the HGR Regulation, patents derived from the cross-border cooperation using PRC genetic resources shall be jointly applied and owned by the cooperating PRC and foreign parties.

Copyright

Copyright in the PRC, including copyrighted software, is principally protected under the Copyright Law of the People's Republic of China (《中華人民共和國著作權法》) which became effective in 1991 and was most recently amended on November 11, 2020 and took effect on June 1, 2021, and related rules and regulations. Under the Copyright Law of the People's Republic of China, the term of protection for copyrighted software is 50 years. The Regulation on the Protection of the Right to Communicate Works to the Public over Information Networks (《信息網絡傳播權保護條例》), which was most recently amended on January 30, 2013, and provides specific rules on fair use, statutory license, and a safe harbor for use of copyrights and copyright management technology and specifies the liabilities of various entities for violations, including copyright holders, libraries and Internet service providers. In order to further implement the Regulations for the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on December 20, 2001 and last amended on January 30, 2013, the National Copyright Administration issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on February 20, 2002, which applies to software copyright registration, license contract registration and transfer contract registration with respect to software copyright.

Trademark

Registered trademarks are protected under the Trademark Law of the People's Republic of China (《中華人民共和國商標法》) which became effective in 1983 and was most recently amended on November 1, 2019 and related rules and regulations. Trademarks are registered with the Trademark Office of China National Intellectual Property Administration. Where registration is sought for a trademark that is identical or similar to another trademark which has already been registered or given preliminary examination in the same or similar category of commodities or services, the application for registration of this trademark may be rejected. Trademark registrations are effective for a renewable ten-year period, unless otherwise revoked.

Domain Name

Domain names are protected under the Administrative Measures on Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology, or MIIT, on August 24, 2017 and effective as of November 1, 2017. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and applicants become domain name holders upon successful registration.

REGULATIONS RELATING TO INFORMATION SECURITY AND PRIVACY PROTECTION

Pursuant to the Civil Code of the People's Republic of China, the personal information of an individual shall be protected. Any organization or individual shall legally obtain the personal information of any person when necessary and ensure the safety of such personal information, and shall not illegally collect, use, process or transmit such personal information, or illegally buy or sell, provide or make public such personal information. A natural person has the privacy right, and provisions on the privacy right shall apply to the private information included in personal information. The Basic Standards for Medical Test Laboratories (for Trial Implementation) (《醫學檢驗實驗室基本標準(試行)》), as promulgated by NHFPC in 2016, provides that medical laboratories must establish information management and patient privacy protection policies. The Measures for the Administration of General Population Health Information (for Trial Implementation) (《人口健康信息管理辦法(試行)》), or the Population Health Information Measures, as promulgated by NHFPC on May 5, 2014, set forth the operational measures for patient privacy protection in medical institutions. The Population Health Information Measures regulate the collection, use, management, safety and privacy protection of general population health information by medical institutions. Medical institutions must establish information management departments responsible for general population health information and establish quality control procedures and relevant information systems to manage this information. Medical institutions must adopt stringent procedures to verify the general population health data collected, timely update and maintain the data, establish policies on the authorized use of this information, and establish safety protection systems, policies, practice and technical guidance to avoid divulging confidential or private information.

The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》), promulgated by the SCNPC on November 7, 2016 and effective on June 1, 2017, requires network operators to adopt technical and other necessary measures to ensure security of personal data and safeguard against information leakage, damage or loss. On June 10, 2021, the SCNPC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), or the Data Security Law, which became effective on September 1, 2021. The Data Security Law provides that "data" refers to any recording of information by electronic or other means and "data processing" includes the collection, storage, use, processing, transmission, availability and disclosure of data, etc. Data processors shall establish and improve the whole-process data security management rules, organize and implement data security training as well as take appropriate technical measures and other necessary measures to protect data security.

To support the implementation of the Data Security Law, on December 28, 2021, the Cyberspace Administration of China, or CAC, jointly with other 12 governmental authorities, issued the revised Measures for Cybersecurity Review (《網絡安全審查辦法》), or the Revised CAC Measures, which became effective on February 15, 2022. Pursuant to the Revised CAC Measures, a cybersecurity review is required when national security has been or may be affected where a critical information infrastructure operator (the "**CIIO**") (關鍵信息基礎設施運營者) purchases network products and services, and an online platform operator carries out data processing activities. Moreover, the Revised CAC Measures also provide that an online platform operator (網絡平台運營者) possessing personal information of more than one million users that applies for listing abroad, shall make declaration for cybersecurity review with the Office of Cybersecurity Review. On July 30, 2021, the State Council promulgated the Regulations for Safe

Protection of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》) (the "CII Regulation") which came into effect on September 1, 2021. Pursuant to the CII Regulation, critical information infrastructure refers to important network infrastructure and information system in public telecommunications, information services, energy sources, transportation and other critical industries and domains, in which any destruction or data leakage will have severe impact on national security, the nation's welfare, the people's living and public interests. The CII Regulation also stipulates the procedures for determining critical information infrastructure. It provides that competent authorities shall promulgate detailed rules in designating critical information infrastructure, identify critical information infrastructure in the relevant industries, and notify operators of such critical information infrastructure in a timely manner. As of the Latest Practicable Date, the responsible authorities had not promulgated any implementation provisions or identification rules which include ICL industry in the relevant scope of "critical information infrastructure". In addition, as of the Latest Practicable Date, we had not been notified by any authorities of being classified as a CIIO, involved in any cybersecurity review or received any investigation, inquiry, notice, warning or sanctions by any governmental authorities on such basis. Based on the foregoing, our Directors believe that we should not be classified as a CIIO. In addition, on March 14, 2022, our PRC Legal Advisor and the PRC legal advisor to the Joint Sponsors conducted a telephone consultation with the China Cybersecurity Review Technology and Certification Center (中國網絡安全審查技術與認證中心) (the "**Center**"), the department responsible for accepting cybersecurity review applications under the guidance of the Cybersecurity Review Office. During the consultation, our PRC Legal Advisor and the PRC legal advisor to the Joint Sponsors have informed the Center our proposed [**REDACTED**] plan, and the Center confirmed that [**REDACTED**] does not fall within the scope of "listing abroad" under the Revised CAC Measures, and therefore we are not required to proactively apply for cybersecurity review with respect to our proposed [**REDACTED**]. Our PRC Legal Advisor is of the view that the Center is the competent authority for the Consultation, and the staff who responded our inquires during the Consultation is the duly designated person in the Center to handle public inquiries. As such, our PRC Legal Advisor is of the view that [**REDACTED**] does not fall within the scope of "listing abroad" under the Revised CAC Measures and thereby we are not required to proactively apply for cybersecurity review with respect to the proposed [**REDACTED**].

On November 14, 2021, the CAC issued the Regulations on the Administration of Cyber Data Security (Consultation Draft) (《網絡數據安全管理條例(徵求意見稿)》) (the "**Draft Data Security Regulations**") for public comments. The Draft Data Security Regulations have set out requirements on matters such as the protection of personal information, security of important data, security management of cross-border data transfer, application for cybersecurity review and obligations of internet platform operators. According to the Draft Data Security Regulations, a data processor shall apply for a cybersecurity review if it involves the following activities: (i) the merger, reorganization or separation of internet platform operators that possess a large number of data resources related to national security, economic development or public interests, that influence or may influence national security; (ii) seeking listing abroad that process personal information of more than one million users; (iii) seeking listing in Hong Kong, which will influence or may influence the national security; (iv) other data processing activities that will influence or may influence national security. However, the Draft Data Security Regulations provides no further explanation or interpretation for "influence or may influence national security". Given that as of the Latest Practicable Date, the Draft Data Security Regulations were released for public comments only and has not come into effect and we are still in the process of evaluating the applicability of the various requirements under the Draft Data Security Regulations to our business, it is impractical for us to predict the impact of the Draft Data Security Regulations at the current stage. We will closely monitor the rule-making process and will assess and determine whether we are required to apply for the cybersecurity review once the Draft Data Security Regulations is formally promulgated.

REGULATIONS RELATING TO ADVERTISEMENTS

Pursuant to the Advertisement Law of the People's Republic of China (《中華人民共和國廣告法》), which was promulgated by SCNPC on October 27, 1994 and effective from February 1, 1995 and latest amended on April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements on medical devices shall be reviewed by relevant authorities in accordance with applicable rules before being published.

REGULATIONS RELATING TO ANTI-BRIBERY

Since early 1990s, the legislative authorities at different levels in China have promulgated certain laws and regulations in respect of commercial bribery. According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) (the "**Anti-Unfair Competition Law**") promulgated by SCNPC, as amended and effective as of April 23, 2019, unfair competition is defined as an act in which an operator violates the provisions of the Anti-Unfair Competition Law in its production and operation activities, disturbs the market competition order and damages the legitimate rights and interests of other operators or consumers. According to the Anti-Unfair Competition Law, business operators shall abide by the principles of voluntariness, equality, fairness and integrity and abide by laws and business ethics in their market transactions. Operators who violate the provisions of the Anti-Unfair Competition Law shall be subject to corresponding civil, administrative or criminal liabilities according to the specific circumstances.

Pursuant to the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) (the "**Prohibition Commercial Bribery Provisions**") promulgated by the former State Administration of Industry and Commerce on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which "other means" refer to the means used to provide any types of benefits other than money or property, such as offering overseas or domestic travel. Any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or a competitive advantages for the business operator.

Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases. According to the Anti-Unfair Competition Law, if business operator commits bribery, regulatory authorities may impose fines of more than RMB100,000 and less than RMB3,000,000 depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated. According to the Prohibition Commercial Bribery Provisions, regulatory authorities may impose fines depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated. According to the PRC Criminal Law (《中華人民共和國刑法》), which was latest amended by the SCNPC on December 26, 2020 and came into effect on March 1, 2021, anyone who offers money or property to national servants for the purposes of seeking illegitimate benefits may commit a criminal offence and may be imposed on criminal penalty.

REGULATIONS RELATING TO TAX

PRC Enterprise Income Tax

The PRC enterprise income tax, or EIT, is calculated based on the taxable income determined under the applicable EIT Law of the People's Republic of China (《中華人民共和國企業所得稅法》) and its implementation rules, both of which became effective on January 1, 2008 and were most recently amended on December 29, 2018 and April 23, 2019, respectively. Taxpayers consist of resident enterprises and non-resident enterprises. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident

enterprises have not formed permanent establishments or premises in mainland China, or if they have formed permanent establishment institutions or premises in mainland China but there is no actual relationship between the relevant income derived in mainland China and the established institutions or premises set up by them, the enterprise income tax is, in that case, set at the rate of 10% for their income sourced from inside mainland China. The EIT Law and its implementation rules permit certain High and New Technologies Enterprises, or HNTEs, to enjoy a reduced 15% enterprise income tax rate if they meet certain criteria and are officially acknowledged.

PRC Value Added Tax

Pursuant to the Provisional Regulations on Value-Added Tax of the People's Republic of China (《中華人民共和國增值税暫行條例》), which were promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017, and the Implementation Rules for the Provisional Regulations on Value-Added Tax of the People's Republic of China (《中華人民共和國增值税暫行條例實施細則》), which were promulgated by the Ministry of Finance, or MOF, on December 25, 1993 and latest amended on October 28, 2011 and became effective on November 1, 2011, entities and individuals engaging in sale of goods, provision of processing services, repairs and replacement services, sales of services, intangible assets or real property, or importation of goods within the territory of the PRC shall pay value-added tax, or the VAT.

On March 23, 2016, MOF and the State Taxation Administration of the PRC, or STA, jointly issued the Circular on the Pilot Program for Overall Implementation of the Collection of Value Added Tax Instead of Business Tax (《關於全面推開營業税改徵增值税試點的通知》), or the Circular 36, which took effect on May 1, 2016. Pursuant to the Circular 36, all of the companies operating in construction, real estate, finance, modern service or other sectors which were required to pay business tax are required to pay VAT, in lieu of business tax. A VAT rate of 6% applies to revenue derived from the provision of certain services. Unlike business tax, a taxpayer is allowed to offset the qualified input VAT paid on taxable purchases against the output VAT chargeable on the revenue from services provided.

On March 20, 2019, MOF, STA and GACC issued the Announcement on Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》), or the Announcement 39, which came into effect on April 1, 2019, to further slash VAT rates. According to the Announcement 39, (i) the 16% or 10% VAT previously imposed on sales and imports by general VAT taxpayers is reduced to 13% or 9% respectively; (ii) the 10% purchase VAT credit rate allowed for the procured agricultural products is reduced to 9%; (iii) the 13% purchase VAT credit rate allowed for the agricultural products procured for production or commissioned processing is reduced to 10%; and (iv) the 16% or 10% export VAT refund rate previously granted to the exportation of goods or labor services is reduced to 13% or 9%, respectively.

REGULATIONS RELATING TO FOREIGN EXCHANGE AND DIVIDEND DISTRIBUTION

Foreign Exchange Regulation

The principal regulations governing foreign currency exchange in China are the Regulations on Foreign Exchange Administration of the People's Republic of China (《中華人民共和國外匯管理條例》), promulgated on January 29, 1996, last revised and effective on August 5, 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency denominated loans or foreign currency is to be remitted into China under the capital account, such as a capital increase or foreign currency loans to our PRC subsidiaries.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》), as latest amended in December 2019, which substantially amends and simplifies the foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of Renminbi proceeds by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible previously. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents (《關於印發<外國投資者境內直接投資外匯管理規定>及配套文件的通知》) in May 2013, as latest amended in December 2019, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches. In February 2015, SAFE promulgated the Circular of Further Simplifying and Improving the Policies of Foreign Exchange Administration Applicable to Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), or the Circular 13, which became effective on June 1, 2015. Under the Circular 13, the foreign exchange procedures are further simplified, and foreign exchange registrations of direct investment will be handled by the banks designated by the foreign exchange authority instead of SAFE and its branches. However, the foreign invested enterprises were still prohibited by the Circular 13 to use the Renminbi converted from foreign currency-registered capital to extend entrustment loans, repay bank loans or inter-company loans.

On June 9, 2016, SAFE issued the Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《關於改革和規範資本項目結匯管理政策的通知》), or the Circular 16, which took effect on the same day. The Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding Renminbi obtained from foreign exchange settlement are not restricted from extending loans to related parties or repaying the inter-company loans (including advances by third parties).

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification (《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》), or the Circular 3, which took effect on the same day. The Circular 3 sets out various measures, including the following: (i) relaxing the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation, including (a) expanding the scope of foreign exchange settlement for domestic foreign exchange loans, (b) allowing the capital repatriation for offshore financing against domestic guarantee, (c) facilitating the centralized management of foreign exchange funds of multinational companies, and (d) allowing offshore institutions within pilot free trade zones to settle foreign exchange in domestic foreign exchange accounts; and (ii) tightening genuineness and compliance verification of cross-border transactions and cross-border capital flow, including (a) improving the statistics of current account foreign currency earnings deposited offshore, (b) requiring banks to verify board resolutions, tax filing form, and audited financial statements before wiring foreign invested enterprises' foreign exchange distribution above US$50,000, (c) strengthening genuineness and compliance verification of foreign direct investments, and (d) implementing full scale management of offshore loans in Renminbi and foreign currencies by requiring the total amount of offshore loans be no higher than 30% of the onshore owner's equity shown on its audited financial statements of the last year.

On October 23, 2019, SAFE issued the Circular on Further Facilitating Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), or the Circular 28, which took effect on the same day. The Circular 28 allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, provided that such investments do not violate the negative list and the target investment projects are genuine and in compliance with laws. Since the Circular 28 was issued only recently, its interpretation and implementation in practice are still subject to substantial uncertainties.

To use our offshore foreign currency to fund our PRC operations, we will apply to obtain the relevant approvals of SAFE and other PRC government authorities as necessary. Our PRC subsidiary's distributions to their offshore parents and our cross-border foreign exchange activities are required to comply with the various requirements under the relevant foreign exchange rules.

SAFE Circular 37

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《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》), or the SAFE Circular 37, on July 4, 2014, which replaced the former circular commonly known as the "SAFE Circular 75" (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) promulgated by SAFE on October 21, 2005. The SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with their legally owned assets or interests in domestic enterprises or offshore assets or interests, referred to in the SAFE Circular 37 as a "special purpose vehicle". The SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiary of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls. On February 13, 2015, SAFE released the Circular 13, under which local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, from June 1, 2015. There exist substantial uncertainties with respect to its interpretation and implementation by governmental authorities and banks.

Regulation of dividend distribution

Under our current corporate structure, our Cayman Islands holding company may rely on dividend payments from our PRC subsidiary, which is a wholly foreign-owned enterprise incorporated in the PRC, to fund any cash and financing requirements we may have. The principal laws, rules and regulations governing dividend distribution by wholly foreign-owned enterprise in the PRC are the Company Law of the People's Republic of China (《中華人民共和國公司法》), as latest amended on October 26, 2018, the 2019 Foreign Investment Law and its implementing rules. Under these laws, rules and regulations, wholly foreign-owned enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A wholly foreign-owned enterprise is required to set aside as general reserves at least 10% of their after-tax profit, until the cumulative amount of their reserves reaches 50% of their registered capital. 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.

REGULATIONS RELATING TO LAND USE RIGHTS OF REAL ESTATE PROPERTY

The Civil Code of the People's Republic of China (《中華人民共和國民法典》), the Land Administration Law of the People's Republic of China (《中華人民共和國土地管理法》) enacted by SCNPC on June 25, 1986 with its latest amendment effective on January 1, 2020, the Regulations on the Implementation of the Land Administration Law of the People's Republic of China (《中華人民共和國土地管理法實施條例》) promulgated by the State Council on December 27, 1998 with its latest amendment on July 2, 2021, and the Law on the Administration of Urban Real Estate of the PRC (《中華人民共和國城市房地產管理法》) passed by the SCNPC on July 5, 1994 with its latest amendment effective on January 1, 2020, mainly govern the use rights of the state-owned land in the PRC.

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》), in order to establish construction land use rights, registration shall be completed with the registrar. A holder of construction land use rights shall reasonably use the land and may not alter the purpose of land use. Approval of the relevant administrative department shall be obtained if altering the purpose of land use.

Pursuant to the Land Administration Law of the People's Republic of China (《中華人民共和國土地管理法》) and the Regulations on the Implementation of the Land Administration Law of the People's Republic of China (《中華人民共和國土地管理法實施條例》), the state implements a land use control system and shall formulate an overall land utilization plan to specify land use. Any entity or individual must use land in strict accordance with the purposes of land use as specified in the overall land utilization plan. Construction entities shall use state-owned land according to the stipulations of the land use right assignment contract or according to the provisions of the approval documents relevant to the allocation of land use rights. The conversion of the construction purposes of the land shall receive the consent of the competent land administrative authority and be submitted to the people's governments that originally granted land use approval. When changing the purpose of land within urban planning areas, consent shall be obtained from the relevant urban planning administration department before submission; without such approvals, the use of land specified in the relevant overall land utilization plan shall not be changed. Under these regulations, failure to comply with the approved usage may subject to fines or other penalties, including potentially being required by the relevant land administrative authority to return the land.