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### CHINA

The medical device industry in the PRC is subject to strict and extensive regulation and review by governmental authorities. In the PRC, SFDA is the principal government authority that regulates and supervises matters related to the manufacturing and selling of medical devices, and SFDA is also responsible for promulgating rules and formulating policies with regard to medical devices. NDRC and MOH also issue regulations and implementation rules with respect to the pricing and tender process of medical devices.

As a manufacturer of medical devices, we are subject to regulations and oversight by different levels of SFDA, NDRC and MOH. The principal regulations that apply to us include the Regulations for the Supervision and Administration of Medical Devices (醫療器械監督管理條例), the Rules for the Supervision and Administration of the Production of Medical Devices (醫療器械生產監督管理辦法), the Rules for the Administration of the Registration of Medical Devices (醫療器械註冊管理辦法) and the Rules for the Administration of Medical Device Operation Enterprise Permits (醫療器械經營企業許可證管理辦法). We are also subject to other laws and regulations which are applicable to manufacturers in general.

In connection with the manufacturing of our products, we are subject to various SFDA requirements including obtaining production permits, product registrations and export registrations, adverse event reporting and compliance with clinical testing standards, manufacturing practices, quality standards, applicable industry standards and advertising and packaging standards.

Set out below is a summary of the principal rules and regulations that are applicable to us.

#### **SFDA requirements**

##### *Classification of medical devices*

In China, medical devices are classified into three different categories, Class I, Class II and Class III, based on the invasiveness of and risks associated with each medical device. The classification of a medical device, among other things, determines whether a manufacturer needs to obtain a production permit in order to manufacture this device and the level of regulatory authority that has jurisdiction over such permit. Classification of a device also determines the types of registration required and the level of regulatory authority that has jurisdiction over the registration.

Class I devices are those with low risks to the human body and are subject to “general regulatory control.” Class I devices are regulated by the provincial level of SFDA where the manufacturer is located. Class II devices are those with medium risks to the human body and are subject to “special regulatory control.” Class II devices require product certification, usually through a quality system assessment, and are regulated by the provincial level of SFDA where the manufacturer is located. Class III devices are those with high risks to the human body, such as life sustaining, life-supporting or implantable devices. Class III devices require product certification, usually through a quality system assessment, and are regulated by SFDA under the strictest regulatory control. For Class II devices and Class III devices, clinical trials are required before regulatory approvals are granted.

All our products, including stents, catheters and insulin pumps are classified as Class III devices, and therefore are subject to all regulatory controls governing Class III devices, except for our radial artery hemostat which is a Class I device. Currently, we do not have any Class II devices.

##### *Production permit*

A manufacturer of medical devices must obtain a medical device production permit from the provincial level of SFDA before commencing the manufacture of Class II or Class III devices, whereas a manufacturer of

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medical devices must do a filing with the provincial level of SFDA before commencing the manufacture of Class I devices. A production permit is valid for five years and is renewable upon expiration. To renew a production permit, a manufacturer needs to submit to the provincial level of SFDA an application to renew the permit along with required information six months before the expiration date of the permit. Our production permits, held through MP Shanghai and MP Lifesciences Beijing, are valid through December 2010 and March 2011, respectively, and we expect to renew them upon their expiration. We have also completed the necessary filing with the provincial level of SFDA in Shanghai.

### *Registration requirements; clinical trials*

A manufacturer of medical devices is required to have its own product registration standards for the safety and efficacy of each medical device, which are based on relevant state and international standards and approved by SFDA. Before a medical device can be manufactured for commercial distribution, a manufacturer must complete medical device registration by proving that the safety and efficacy of the medical device meet the standards set by SFDA. SFDA requires manufacturers to apply for and to obtain in advance a favorable test result for the device from a test center recognized by SFDA. The test center conducts animal and laboratory testing by strictly following the applicable product registration standards. If the testing results are acceptable according to the applicable product registration standards, the manufacturer may then begin the clinical trial. See “Business — Clinical trials” in this prospectus. After the clinical trial of a Class III device, the provincial level of SFDA, after receiving an application of inspection, will conduct an on-site inspection of the quality management system of the manufacturer and the integrity of the clinical trial conducted, and within 85 working days of receiving such application, will deliver an inspection report to the manufacturer. A registration application for a Class II or Class III device must provide the requisite pre-clinical and clinical trial data and information, including the foregoing inspection report for a Class III device, on the device and its components regarding, among other things, device design, manufacturing and labeling. For a Class III device, SFDA will conduct a technical review on such data to ensure the medical device meet the safety and efficacy standards set by SFDA, followed by an administration review to ensure that the registration process has been in compliance with relevant laws and regulations of China. The provincial level of SFDA, within 60 days of receiving an application for the registration of a Class II device, and SFDA, within 90 days of receiving an application for the registration of a Class III device, will notify the applicant whether the application for registration is approved. If approved, a registration certificate will be issued within ten days of the notification. If the provincial level of SFDA or SFDA, as the case may be, requires supplemental information, the approval process may take much longer. A registration is valid for four years and is renewable upon expiration. To renew a registration for a Class II or Class III device, the manufacturer needs to submit to the provincial level of SFDA or SFDA, as the case may be, an application for renewal six months prior to the expiration date. In addition to medical device registration, a manufacturer of medical device should also obtain a China Compulsory Certification for a Class III device as discussed in “— Quality supervision” below.

SFDA may change its policies, adopt additional regulations, revise existing regulations or tighten enforcement, each of which could block or delay the approval process for a medical device.

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As of the Latest Practicable Date, we had received SFDA approvals for the production and nationwide sale of the following products in China, 15 of which we currently offer for sale in China:

Type of Device	Brand	Product	Classification	Expiration
Cardiovascular Devices	Firebird 2	Drug-eluting cobalt-chromium stent system	Class III device	January 14, 2012
	Firebird	Drug-eluting stent system	Class III device	January 31, 2012
	Mustang	Bare-metal stent system	Class III device	May 4, 2012
	Pioneer	PTCA balloon dilatation catheter	Class III device	April 12, 2014
	—	Angiographic catheter	Class III device	May 25, 2010 <sup>(1)</sup>
	—	Single-use accessory devices for use with intravascular catheter	Class III device	December 5, 2011
Other Vascular Devices	Cronus	Operational stent graft system	Class III device	November 16, 2013
	Crownus	Peripheral stent system	Class III device	December 3, 2013
	Apollo	Intracranial stent system	Class III device	January 31, 2012
	Aether	Distal protective device	Class III device	March 14, 2010 <sup>(1)</sup>
	Hercules T	TAA stent graft system	Class III device	July 7, 2010 <sup>(1)</sup>
	Aegis T	TAA stent graft system	Class III device	July 13, 2009 <sup>(1)</sup>
	Hercules B	AAA stent graft system	Class III device	August 23, 2013
	Aegis B	AAA stent graft system	Class III device	July 14, 2009 <sup>(1)</sup>
	Radial artery hemostat	Radial artery hemostat	Class I device	January 20, 2014
Electrophysiology Device	FireMagic	Ablation catheter	Class III device	July 27, 2013
Diabetes Device	La Fenice	Insulin pump	Class III device	June 11, 2011

Note:

(1) Applications for the extension of approval for these products have been submitted to SFDA and are being processed by SFDA. Pursuant to the relevant notices issued by SFDA in February 2009 and April 2010, we are allowed to continue producing and selling these products while SFDA processes the applications, and we expect to obtain the approvals in the last quarter of 2010 or the first half of 2011. Our PRC counsel, Jun He Law Offices, has advised that there is no legal impediment to obtain such approvals.

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### *Regulation of medical device distribution*

A distributor of medical devices must obtain a medical device distributing enterprise permit from the provincial level of SFDA before commencing the distribution of Class II or Class III devices, whereas a distributor of medical devices must do a filing with the provincial level of SFDA before commencing the distribution of Class I devices. Such permit is valid for five years and is renewable upon expiration. To renew such permit, a distributor needs to submit to the provincial level of SFDA an application to renew the permit along with required information six months before the expiration date of the permit. As all the products we currently offer are Class III devices, we sell these products through distributors who have obtained the medical device distributing enterprise permits. We have obtained SFDA approval for our radial artery hemostat, a Class I device, and expect to commercially launch such product as soon as the last quarter of 2010 through distributors who have made the requisite filing with the provincial level of SFDA.

### *Export registration*

SFDA maintains a registration system for the export of medical devices. Before a manufacturer of medical devices, including PRC domestic companies and FIEs, can export any medical device, it must obtain from SFDA an export registration certificate. The export registration for Firebird and Firebird 2 is valid through November 2011 and, subject to compliance with the relevant regulations, is renewable upon expiration.

### *Advertising and promotion*

In order to obtain a permit for the advertising and promotion of medical devices (醫療器械廣告批准文號), a manufacturer of medical devices needs to submit an application to SFDA or the provincial level of SFDA to obtain an advertising permit for medical devices. In addition, the content of advertisements for medical devices is subject to certain guidelines approved by SFDA or the provincial level of SFDA.

### *Continuing SFDA regulation*

We are subject to continuing supervision by SFDA. In the event of significant modification to an approved medical device, its labeling or its manufacturing process, a new pre-market approval or pre-market approval supplement may be required. Our products are subject to, among others, the following regulations:

- SFDA's quality system regulations which require manufacturers to create, implement and follow certain design, testing, control, documentation and other quality assurance procedures;
- medical device reporting regulations, which require that manufacturers report to SFDA certain types of adverse reaction and other incidents involving their products; and
- SFDA's general prohibition against promoting products for unapproved uses.

During the Track Record Period, we have reported to SFDA a few adverse incidents primarily involving the use of Firebird and Firebird 2, including the loosening up of stents from the catheter delivery system, breakdown of stent, restenosis and fatalities of patients (which we believe were not directly caused by our products). As these incidents did not affect our compliance with regulatory requirements, no penalty or enforcement action was imposed by SFDA, and these incidents did not affect our business, financial condition and results of operation. Our Directors confirm that we were not subject to any claims or litigation concerning the quality of our products during the Track Record Period. In addition, we did not make any recalls of our products during the Track Record Period.

Class II and III devices may also be subject to special controls applicable to them, such as supply purchase information, performance standards, quality inspection procedures and product testing devices which

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may not be required for Class I devices. Our Directors confirm that we are in compliance with the applicable SFDA guidelines, but we could be required to change our compliance activities or be subject to other special controls if SFDA changes or modifies its existing regulations or adopts new requirements.

We are also subject to inspection and market surveillance by SFDA to determine compliance with regulatory requirements. If SFDA decides to enforce its regulations and rules, the agency can institute a wide variety of enforcement actions such as:

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- the imposition of operating restrictions, partial suspension or complete shutdown of production;
- revocation of our existing registrations, approvals and permits; and
- criminal prosecution.

### **Pricing and tender process**

In China, national and provincial price administration authorities publish price control lists, and may, from time to time, restrict retail prices for certain medical devices. Such restrictions are usually in the form of pricing guidelines. Manufacturers of medical devices are required to set the retail prices of their products below the relevant maximum prices contained in these pricing guidelines. The relevant price administration authorities typically determine the maximum retail price of a product on the basis of its average unit cost among various manufacturers of the product.

In China, public hospitals and healthcare institutions are required to purchase high value medical supplies, including our vascular products, at prices established through a periodic tender process. In August 2004, MOH promulgated the Trial Working Plan for Centralized Purchasing of High Value Medical Supplies by Health Institutions in Eight Provinces and Municipalities (8省市醫療機構高值醫用耗材集中採購試點工作方案), pursuant to which MOH and its counterparts in eight provinces and municipalities, including Beijing and Shanghai, organized and supervised the negotiation of retail prices with suppliers through a centralized bidding process to establish the retail prices for the healthcare institutions within these provinces and municipalities. Hospitals and healthcare institutions in other provinces generally followed the prices established in these tenders.

In June 2007, MOH issued a Notice regarding Further Enhancing the Administration of Centralized Purchasing of Medical Devices (衛生部關於進一步加強醫療器械集中採購管理的通知), pursuant to which MOH carried out a nationwide tender to set medical device retail prices for all hospitals and healthcare institutions in China.

In January 2010, MOH issued a Notice regarding Centralized Purchasing of High Value Medical Supplies (衛生部辦公廳關於全國高值醫用耗材集中採購有關事項的通知), which states that the period of nationwide tender from October 1, 2008 to September 30, 2009 would be extended to September 30, 2010. After September 30, 2010, MOH will institute a decentralized approach to tenders whereby individual provinces and municipalities will be authorized to hold their own tenders.

Moreover, in November 2009, NDRC, MOH and MOHRSS jointly issued a Notice of Opinion on Reform of Pricing System of Pharmaceuticals and Medical Services (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), pursuant to which NDRC will strengthen its intervention in the pricing of medical devices (including high value medical devices), limit the profit margins of the participants in the supply chain for medical devices and periodically announce market price information of medical devices.

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During the Track Record Period, all products which we submitted in connection with the tenders described above have been included in the tenders and approved for sale.

### **Governmental insurance reimbursement program**

Pursuant to the Decision of the State Council on the Establishment of Basic Medical Insurance System for Urban Employees (國務院關於建立城鎮職工基本醫療保險制度的決定) issued in December 1998, all employers in urban cities are required to enroll their employees in the basic medical insurance system and the insurance premium is jointly contributed by the employers and employees on a monthly basis. Currently, most participants of this national basic medical insurance system are urban residents who are employed or retired from an enterprise. These participants are eligible for full or partial reimbursement of the cost of medicine, medical service and diagnosis and treatment designated by the PRC government. Patients who are participants of the basic medical insurance system tend to choose those medical devices covered by the medical insurance to save their cost in connection with diagnosis and medical treatment.

In accordance with a Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standard of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance System (關於印發城鎮職工基本醫療保險診療專案管理、醫療服務設施範圍和支付標準意見的通知) jointly issued by the Ministry of Labor and Social Security, the National Development and Planning Commission, the Ministry of Treasure and the General Administration of Chinese Traditional Medicine in June 1999, vascular stents and other implantation materials in the body are classified as an item of diagnosis and medical treatment which could be partially reimbursed through basic medical insurance system. However, the actual devices that are covered under the basic medical insurance system and the actual insurance coverage of reimbursement level vary from region to region, as local government approvals for such coverage must be obtained in each geographic region in China.

As part of the healthcare reform plan, the PRC government aims to enlarge the scope of participants of medical insurance system from urban employees to almost all urban and rural residents, see “- Healthcare reform plan” below.

A majority of our products are subject to reimbursement from governmental health insurers in most major provinces and municipalities in China, including Firebird and Firebird 2. Our other products which are currently not eligible for reimbursement from governmental insurers in certain provinces may be included in insurance coverage from time to time, subject to PRC government policies and local government approvals.

### **Healthcare reform plan**

In January 2009, the Chinese government approved in principle a healthcare reform plan to address the affordability of healthcare services, the rural healthcare system and healthcare service quality in China. In March 2009, the State Council issued a Notice regarding Issuance of Key Implementation Scheme on Reform of Medical and Sanitary System in Recent Period (2009 – 2011) (關於印發醫藥衛生體制改革近期重點實施方案(2009—2011年)的通知) (the “Implementation Scheme”), which calls for, among other things, additional governmental spending on healthcare of RMB850 billion from 2009 to 2011 to support the reform plan. Such government spending is expected to be used primarily to (i) establish a basic healthcare medical insurance regime; (ii) increase the amount of rural and urban population covered by the basic medical insurance system or the new rural cooperative healthcare medical system to at least 90% by 2011; (iii) build a basic medicine system that includes a catalog of necessary drugs produced and distributed under government control and supervision; and (iv) enhance healthcare facilities, including building clinics and hospitals. The Implementation Scheme directs relevant governmental authorities to adopt implementing rules for the reforms

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outlined in the healthcare reform plan. However, the PRC government has not yet provided a concrete timetable nor steps to implement certain aspects of the healthcare reform plan.

The major portion of the increased spending is expected to be directed toward basic healthcare services, including building additional clinics in rural areas. This expenditure is unlikely to have any direct effect on our business in the near term as our products are generally used in advanced treatments for vascular diseases and disorders, which are mainly conducted in Tier III and Tier II hospitals. Although we expect that the improvement in basic health services will result in more patients being diagnosed with cardiovascular and other diseases which can be treated using our products, we cannot predict the long-term effect of China's healthcare reform, including whether spending on catheter laboratories and other facilities where our products are used will increase.

### **Quality management system**

China is implementing certain quality management systems as part of its effort to achieve a general standardization of medical devices. China has developed a system of medical device quality certification, which is not yet compulsory and is currently only recommended for Class III devices. Our principal operating subsidiary, MP Shanghai, obtained ISO 13485 certification from Beijing Hua Guang Certification of Medical Devices Co., Ltd. (formally known as China Quality Certification Center for Medical Devices) for its quality management system of medical devices in 2005, 2007 and 2009.

### **Implementation of GMP**

Although the PRC government has already implemented pharmaceutical good manufacturing practices, which became mandatory in 2004, Good Manufacturing Practices are still not compulsory for medical devices. In December 2009, SFDA issued a series of notices on the implementation of manufacturing quality standards, especially for sterile medical devices and implantable medical devices. Such standards will be formally implemented from January 1, 2011. It is expected that by such time, the implementation of GMP will be extended to all manufacturers of medical devices.

### **Manufacturing safety**

Pursuant to the Law of the PRC on Manufacturing Safety (中華人民共和國安全生產法) which took effect from November 2002, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws and regulations. Manufacturers not fulfilling relevant legal requirements are not permitted to commence their manufacturing activities.

### **Patent law**

According to the PRC Patent Law (中華人民共和國專利法) promulgated on March 12, 1984 and as amended on August 25, 2000 and December 27, 2008, patent protection is divided into three categories: invention patent, utility model patent and design patent. An invention patent is intended to protect a new technical solution relating to a product, process or its improvement. A utility model patent is intended to protect a new technical solution relating to the shape, the structure, or the combination of both shape and structure of a product, which is applicable for functional use. A design patent is intended to protect new designs of the shape, the pattern or the combination of both shape and pattern, or the combination of the color with shape or pattern of a product with aesthetic and industrial application value.

#### ***Invention patent***

The products seeking invention patent protection must possess such characteristics as novelty and innovation, and the grant of an invention patent is subject to disclosure and publication requirements. In the PRC,

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the State Intellectual Property Office of the PRC (“SIPO”) publishes the application 18 months after an application is filed, which may be shortened upon request by the applicant. The SIPO will conduct a substantive review as requested by an applicant within three years from the filing date of the application or if necessary at its discretion to grant the invention patent, issue the certificate of invention patent, announce and register the patent if there is no cause for rejection of the application of the invention patent after substantive review and make a decision. The term of protection is 20 years from the filing date of application.

Once an invention patent is granted, unless otherwise permitted by law, no individuals or entities are permitted to engage in the manufacture, use, sale, offer to sale or import of the product protected by such patent or otherwise engage in the manufacture, use, sale, offer to sale or import of the product directly derived from applying the method protected by such patent, without consent of the patent holder.

### *Utility model patent*

The products seeking utility model patent protection must possess such characteristics as novelty and innovation. A utility model patent is granted and registered upon application unless there are reasons for the SIPO to reject the application after its preliminary review. The utility model patent is also subject to the disclosure and publication requirement upon application. The term of protection is ten years from the filing date of the application.

Once a utility model patent is granted, unless otherwise permitted by law, no individuals or entities are permitted to engage in the manufacture, use, sale, offer to sale or import of the product protected by such patent without consent of the patent holder.

### *Design patent*

The products seeking design patent protection must not be the same as or similar to those previously known in domestic or abroad or infringing upon third parties’ legal rights. The application procedure and term of protection are the same as for a utility model patent.

Once a design patent is granted, no individuals or entities are permitted to engage in the manufacture, sale, offer to sale or import of the product protected by such patent without consent of the patent holder.

## **Tax**

PRC enterprise income tax is calculated primarily on the basis of taxable income determined under PRC tax laws and regulations. Prior to January 1, 2008, in accordance with Income Tax of China for Enterprises with Foreign Investment and Foreign Enterprises (中華人民共和國外商投資企業和外國企業所得稅法) (the “FIE Income Tax Law”) and the related implementing rules, FIEs incorporated in the PRC were generally subject to an income tax rate of 33% (30% of state income tax plus 3% local income tax). The FIE Income Tax Law and the related implementing rules provided certain favorable tax treatments to certain FIEs and enterprises which were registered and operated in specified economic development zones or Pudong New Area in the PRC. PRC domestically invested companies were governed by the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法) and were generally subject to an income tax rate of 33%.

In March 2007, NPC adopted the CIT Law that imposes a single uniform income tax rate of 25% for most domestic enterprises and FIEs. The CIT Law became effective on January 1, 2008. It contemplates various transition periods and measures for existing preferential tax policies, including a grace period for as long as five years for FIEs which were entitled to a lower income tax rate before the promulgation of the CIT Law and continued the implementation of preferential tax treatment with a fixed term until the expiration of such fixed term. Moreover, the CIT Law provides that, if an enterprise incorporated outside the PRC has its “de facto



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management organization” located within the PRC, the enterprise may be recognized as a “PRC resident enterprise” and thus may be subject to an enterprise income tax at the rate of 25% on its worldwide income. Under the implementation rules for the CIT Law, “de facto management bodies” is defined as the bodies that have material and overall management control over the business, personnel, accounts and properties of an enterprise. In April 2009, the PRC tax authority promulgated a circular to clarify the criteria for determining whether the “de facto management bodies” are located within the PRC for enterprises incorporated overseas with Controlling Shareholder being PRC enterprises. However, the relevant PRC laws and regulations remain unclear regarding how the PRC tax authorities will treat an overseas enterprise invested or controlled by another overseas enterprise as in our case. Substantially all of our management team members reside in the PRC. If most of them continue to reside in the PRC, our Company may be deemed a PRC resident enterprise and therefore subject to the PRC enterprise income tax at a rate of 25% on our worldwide income.

According to the CIT Law and related regulations, the preferential tax treatments MP Shanghai currently enjoys will remain unchanged during the grace period. MP Shanghai is registered and operates in the Pudong New Area and is entitled to a preferential enterprise income tax rate of 15% for the period from January 1, 2009 to December 31, 2010. In addition, as a wholly foreign-owned enterprise engaged in a manufacturing business, MP Shanghai is entitled to an exemption from the enterprise income tax for two financial years from its first profit-making year from a PRC tax perspective, which were 2004 and 2005, and to a 50% reduction of its applicable enterprise income tax rate for the succeeding three years, which were 2006, 2007 and 2008. As a result, MP Shanghai was exempt from enterprise income tax until 2005, and its enterprise income tax rate for 2006 and 2007 was 7.5%. According to the Notice of the State Council on the Implementation of the Transitional Preferential Policies in respect of Enterprise Income Tax (國務院關於實施企業所得稅過渡優惠政策的通知), the companies which enjoyed a preferential tax rate of 15% before the promulgation of the CIT Law will be subject to a gradual increase of tax rate from 15% to 25% over five years after January 1, 2008, and the tax rate applicable to such companies in 2008, 2009, 2010, 2011 and 2012 is 18%, 20%, 22%, 24% and 25%, respectively. In 2008, MP Shanghai continued to enjoy the tax holiday preferential tax treatment and was entitled to a 50% reduction of its applicable enterprise income tax rate. Therefore, the income tax rate applicable to MP Shanghai was 9% in 2008. In November 2008, MP Shanghai was recognized as a High and New Technology Enterprise and was subject to a preferential tax rate of 15% for 2009 and 2010.

Pursuant to the Provisional Regulation of China on Value Added Tax (中華人民共和國增值稅暫行條例) and its implementing rules, all entities and individuals that are engaged in the sale of goods, the provision of processing, repairs and replacement services and the importation of goods in China are generally required to pay output VAT at a rate of 17% of the gross sales proceeds received, less any deductible input VAT already paid or borne by the entities or individual. Further, when exporting goods, the exporter is exempt from payment of output VAT.

### **Product liability**

The Product Quality Law of the PRC (中華人民共和國產品質量法) was promulgated in February 1993 and amended in July 2000. The Product Quality Law applies to all production activities and sale of any product within the territory of the PRC, and producers and sellers will be liable for product quality in accordance with the Product Quality Law.

In December 2009, NPC promulgated the PRC Tort Liability Law (中華人民共和國侵權責任法), which became effective on July 1, 2010. The Tort Liability Law stipulates tort liabilities relating to, among other things, products, motor vehicle traffic accidents, medical treatment, environmental pollution and high risk operations. Under the Tort Liability Law, a patient who suffers injury from the defect of any drug or medical device can

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claim against either the medical institution or manufacturer. If the patient claims compensation against the medical institution, the medical institution that has paid the compensation will be entitled to reimbursement from the responsible manufacturer.

### Regulation of overseas listings

In August 2006, six PRC regulatory agencies, including MOFCOM, the State Assets Supervision and Administration Commission, the State Administration for Taxation, the State Administration for Industry and Commerce, CSRC and SAFE, jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (關於外國投資者併購境內企業的規定), which became effective on September 8, 2006 and was amended in June 2009. This regulation, among other things, contains certain provisions that purport to require that an offshore SPV, formed for listing purposes through acquisition of PRC domestic interests held by the PRC domestic companies or individuals controlling such SPV, to obtain the approval of CSRC prior to the listing and trading of such SPV's securities on an overseas stock exchange.

On September 21, 2006, CSRC published on its official website procedures regarding its approval of overseas listings by SPVs. CSRC approval procedures require the filing of a number of documents with CSRC and it would take several months to complete the approval process if a waiver is not available.

Our PRC counsel, Jun He Law Offices, has advised that CSRC approval for the Global Offering is not required because our Company is controlled by non-PRC citizens and MP Shanghai was a company with foreign investment before the commencement of our Reorganization and promulgation of the M&A rule in 2006 and thus we have not conducted any merger or acquisition involving a domestic company under the M&A rule. Accordingly, we did not seek and have not obtained CSRC approval.

### Foreign currency exchange

Foreign currency exchange regulation in China is primarily governed by the following rules:

- Foreign Exchange Administration Regulations (1996) (外匯管理條例) (the “Exchange Regulations”), as amended in 2008; and
- Administration Rules of the Settlement, Sale and Payment of Foreign Exchange (1996) (結匯售匯及付匯管理規定), (the “Administration Rules”);

Under the Exchange Regulations, the Renminbi is convertible for current account items, including the distribution of dividends, interest payments, trade and service-related foreign exchange transactions. Conversion of Renminbi for capital account items, such as direct investment, loan, security investment and repatriation of investment, however, is still subject to the approval of SAFE.

Under the Administration Rules, FIEs may only buy, sell and/or remit foreign currencies at those banks authorized to conduct foreign exchange business after providing valid commercial documents and, in the case of capital account item transactions, obtaining approval from SAFE. Capital investments by FIEs outside of China are also subject to limitations, which include approvals by the MOFCOM, SAFE and NDRC.

In addition, in August 2008, SAFE promulgated Circular 142 (國家外匯局綜合司關於完善外商投資企業外匯資金支付結匯管理有關業務操作問題的通知), a notice regulating the conversion by a foreign-invested company of foreign currency into Renminbi by restricting how the converted Renminbi may be used. Circular 142 requires that Renminbi converted from the foreign currency-denominated capital of a foreign-invested company may only be used for purposes within the business scope approved by the applicable governmental authority and may not be used for equity investments within the PRC unless otherwise specifically

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provided for. In addition, SAFE strengthened its oversight over the flow and use of Renminbi funds converted from the foreign currency-denominated capital of a foreign-invested company. The use of such Renminbi may not be changed without approval from SAFE, and may not be used to repay Renminbi loans if the proceeds of such loans have not yet been used. Violations of Circular 142 may result in severe penalties, including substantial fines as set forth in the Exchange Regulations.

### **Dividend distribution**

The principal regulations governing distribution of dividends paid by wholly foreign-owned enterprises include:

- Wholly Foreign-Owned Enterprise Law (1986) (外資企業法), as amended in 2000; and
- Wholly Foreign-Owned Enterprise Law Implementation Rules (1990) (外資企業法實施細則), as amended in 2001.

Under these regulations, FIEs in China may pay dividends only out of net profits, if any, determined in accordance with PRC GAAP. In addition, a wholly foreign-owned enterprise in China is required to set aside at least 10% of its after-tax profit based on PRC GAAP each year to its statutory reserves until the accumulative amount of such reserves reach 50% of its registered capital. These reserves are not distributable as cash dividends. The board of directors of a FIE has the discretion to allocate a portion of its after-tax profits to staff welfare and bonus funds, which may not be distributed to equity owners.

### **Regulation of foreign exchange in certain onshore and offshore transactions**

In October 2005, SAFE issued the Circular on Several Issues Relating to the Administration of Foreign Exchange in Fund-Raising and Return Investment Activities of Domestic Residents Conducted via Offshore Special Purpose Companies (國家外匯管理局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), which became effective as of November 1, 2005.

According to SAFE Circular No. 75:

- prior to establishing or assuming control of an offshore company for the purpose of financing that offshore company with assets or equity interests in an onshore enterprise in the PRC, each PRC domestic resident, whether a natural or legal person, must complete the overseas investment foreign exchange registration procedures with the relevant local SAFE branch;
- an amendment to the registration with the local SAFE branch is required to be filed by any such PRC domestic resident that directly or indirectly holds interests in that offshore company upon either (1) the injection of equity interests or assets of an onshore enterprise to the offshore company, or (2) the completion of any overseas fundraising by such offshore company; and
- an amendment to the registration with the local SAFE branch is also required to be filed by such PRC domestic resident when there is any material change involving a change in the capital of the offshore company, such as (1) an increase or decrease in its capital, (2) a transfer or swap of shares, (3) a merger or division, (4) a long term equity or debt investment, or (5) the creation of any security interests over the relevant assets located in China.

Moreover, SAFE Circular No. 75 applies retroactively. As a result, PRC domestic residents who have established or acquired control of offshore companies that have made onshore investments in the PRC in the past

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are required to complete the relevant overseas investment foreign exchange registration procedures by March 31, 2006.

In May 2007, SAFE issued the Notice of the General Affairs Department of the State Administration of Foreign Exchange on Release of Operative Directives for the “Circular on Several Issues Relating to the Administration of Foreign Exchange in Fund-Raising and Return Investment Activities of Domestic Residents Conducted via Offshore Special Purpose Companies” (國家外匯管理局綜合司關於印發〈國家外匯管理局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〉操作規程的通知), which standardized more specific and stringent supervision on the registration relating to SAFE Circular No. 75 and imposed obligations on onshore subsidiaries of overseas special purpose companies to coordinate with and supervise the beneficial owners of such special purpose companies who are PRC domestic residents to complete the SAFE registration process. Circular No. 106 further defines PRC domestic residents as “natural persons who do not hold legal PRC domestic resident identity but customarily live in the PRC due to the link of economic interest” and these persons mainly fall into the following three categories: (i) natural persons who have permanent residence in the PRC, but are away from their permanent residence temporarily and are staying overseas to travel, study, receive medical treatment, work, or for other reasons, but will return to their permanent residence when such reasons no longer apply; (ii) natural persons who hold a domestically funded equity interest in a domestic enterprise; and (iii) natural persons who originally held a domestic equity interest, and who are still the ultimate holders of such interest, even though such interest has converted into a foreign funded equity interest. Under SAFE Circular No. 75 and relevant foreign exchange regulations, failure to comply with the foreign exchange registration procedures may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including restrictions on the payment of dividends and other distributions to its offshore parent company and the capital inflow from the offshore entity, and may also subject the relevant PRC residents and onshore company to penalties under the PRC foreign exchange administration regulations.

To our knowledge and as advised by our PRC counsel, Jun He Law Offices, one of our Shareholders who is a PRC domestic resident, Dr. Zhaohua Chang (our founder and Director and chairman of our Company), has made the relevant application and filing with the Shanghai branch of SAFE and has obtained the applicable registration and approval required by these SAFE regulations. We have made the relevant applications with the Shanghai branch of SAFE for our other minority shareholders who are PRC domestic residents and became our Shareholders as a result of the exercise of their share options under the Pre-IPO Share Option Schemes. Nevertheless, we were advised by the Shanghai branch of SAFE that these applications would not be accepted and the Shanghai branch of SAFE has ceased accepting applications for registering the overseas investment of PRC domestic residents as a result of exercising share options prior to the listing of a company. The Shanghai branch of SAFE did not explain the reason for not accepting such applications and advised that we could apply for registration after the Listing pursuant to the Share Option Rule which provides that the overseas investments of PRC citizens in the employee share option or share incentive plan of an overseas listed company are required to be registered with SAFE. We cannot assure you, however, that we will be able to obtain applicable registrations and approvals required by these SAFE regulations for our minority shareholders after the Listing. Further, there may be additional PRC domestic resident Shareholders, whose actions we do not control, who are not in compliance with the registration procedures set forth in SAFE Circular No. 75.

### **Regulations on employee share options**

In December 2006, PBOC promulgated the Administrative Measures for Individual Foreign Exchange (個人外匯管理辦法), which set forth the respective requirements for foreign exchange transactions by PRC individuals under either the current account or the capital account. The Implementation Rules of the Administrative Measures for Individual Foreign Exchange (個人外匯管理辦法實施細則), issued in January 2007 by SAFE, specify the approval requirements for PRC citizens who are granted shares or share options by an overseas listed company according to its employee stock ownership plan or stock option plan.

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In March 2007, SAFE promulgated the Processing Guidance on Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Holding Plans or Stock Option Plans of Overseas-Listed Companies (境內個人參與境外上市公司持股計畫和認股期權計畫等外匯管理操作規程). According to the Share Option Rule, if a PRC citizen participates in any employee stock ownership plan or stock option plan of an overseas listed company, a qualified PRC domestic agent or the PRC subsidiaries of such overseas listed company shall, among other things, file, on behalf of such individual, an application with the SAFE to obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the share purchase or share option exercise as PRC domestic individuals may not directly use overseas funds to purchase shares or exercise share options. Such PRC citizen's foreign exchange income received from the sale of shares or dividends distributed by the overseas listed company shall be fully remitted into a collective foreign currency account in the PRC opened and managed by the PRC subsidiaries of the overseas listed company or the PRC agent before distribution to such individual. We and our PRC citizen employees who have been granted share options will be subject to the Share Option Rule upon the Listing. If we or our PRC option holders fail to comply with these regulations, we or our PRC option holders may be subject to fines and other legal or administrative sanctions.

In addition, the State Administration of Taxation has issued certain circulars concerning employee share options. Under these circulars, our employees working in the PRC who exercise share options will be subject to PRC individual income tax.

Our PRC subsidiaries have obligations to file documents related to employee share options with relevant tax authorities and to withhold individual income taxes of those employees who exercise their share options. If our employees fail to pay and we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC governmental authorities.

### **Anti-corruption laws in China**

The PRC government has issued since the early 1990's various laws and regulations with respect to commercial bribery. In 1993, NPC adopted the Anti-Unfair Competition Law (反不正當競爭法) which became effective on December 1, 1993 and provided that a business operator would commit a crime if it offered money or any other bribes in the course of selling or purchasing products. On November 15, 1996, the State Administration for Industry and Commerce of the PRC ("SAIC") issued the Interim Rules on Prohibition of Commercial Bribery (關於禁止商業賄賂行為的暫行規定) ("Order 60"), which provided that the act of commercial bribery includes offering money, goods, free tours, and unrecorded rebate sales commission in secret to any person when selling or buying products. In accordance with the Anti-Unfair Competition Law and Order 60, SAIC (or its local counterparts), being the principal government authority that supervises matters relating to unfair competition and commercial bribery in China, has the power to impose fines in an amount ranging from RMB10,000 to RMB200,000 and to confiscate the illegal gains of a business operator when convicted of commercial bribery. In addition, if any entity or individual offers any property to any government officials for the purpose of seeking illegitimate gain or interests, such act would be considered a crime under the PRC Criminal Law and become punishable by the relevant PRC governmental authorities.

### ***Historical corruption in the PRC healthcare and food products industry***

Various media reports indicated that criminal prosecutors were starting in around 2002 to receive information to the effect that some officials within SFDA were corrupt. The corruption often involved SFDA officials being paid in return for approval of products prior to their commercialization. In some cases, SFDA officials abused their position by requesting payments to approve products which already satisfied SFDA's technical requirements, while in other cases payments were paid in connection with counterfeit or substandard products. At that time, there was also a growing list of scandals involving counterfeit or contaminated food and drugs originating in China, and many media reports circulated indicating that corruption in China was rampant and contributed to these problems.

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During this period, a number of PRC government officials including Premier Wen Jiabao acknowledged that the Chinese healthcare industry was in a state of disorder, and the central government initiated an anti-corruption drive in 2007 to ensure food and medicine safety. The PRC Ministry of Supervision, which is responsible for supervising the different departments of the State Council, stated it would target “unhealthy practices” in the industry. According to the Ministry of Supervision, the cost of corruption in the healthcare sector was estimated to be RMB606.0 million in 2007, based on 2,535 commercial cases it investigated in the prior year. There were also arrests and criminal prosecutions of a number of high ranking SFDA officials, including Zheng Xiaoyu who had been the head of the SFDA from 1998 to 2005. In May 2007, Mr. Zheng was sentenced to death for accepting bribes (in cash, car, down payments of apartments, decorations and furniture, etc.) totaling RMB6.5 million from eight pharmaceutical companies directly or indirectly through his wife and son, in exchange for, among other things, approving the sale of counterfeit medical drugs during his tenure. Mr. Zheng appealed but the original ruling was affirmed in June 2007, and he was executed in July 2007.

In addition, two of Mr. Zheng’s subordinates, Cao Wenzhuang (whose signature was a required part of the approval process in respect of the issuance of the approval certificate for drugs) and Hao Heping (whose signature was a required part of the approval process in respect of the issuance of the approval certificate for medical devices), were also prosecuted. Cao Wenzhuang was the director of the Division of Drug Registration of SFDA. In July 2007, Mr. Cao was sentenced to death with a two-year reprieve for accepting bribes in cash totaling RMB2.4 million from two pharmaceutical companies. Mr. Hao was the director of the Division of Medical Devices of SFDA during this period. In November 2006, Mr. Hao was found guilty of, among other things, accepting bribes and was sentenced to 15 years in prison. In March 2007, the original ruling was affirmed. The bribes included RMB50,000 in cash, a RMB250,000 car, RMB500,000 in golf membership cards and RMB200,000 in decorations, which were provided by several domestic medical device manufacturers, including our Company and another company which was at the time, and remains, listed on the Hong Kong Stock Exchange. Mr. Hao’s wife was also involved and sentenced to five years in prison. The Chinese media reported that Messrs. Cao and Hao had been secretaries of Mr. Zheng prior to their appointment to SFDA and were therefore considered to have a close and personal relationship with him. The Chinese media also reported that from 2005 to 2007, various other SFDA officials were arrested and sentenced for taking bribes.

It was in this environment of serious corruption inside SFDA that our Company became involved in Mr. Hao’s case, as described in more detail in “Business — Special Incident” and “Business — Legal Proceedings and Compliance — Legal implications of special incident” in this prospectus. Notwithstanding our involvement in Mr. Hao’s case, however, all of the products we have offered for sale in China have met, and currently meet, SFDA’s requisite technical standards of safety and efficacy.

### *SFDA reforms since 2007*

To address the corruption problems within SFDA and related food and medicine safety problems, the PRC government took a series of measures with regard to SFDA starting in 2007, including:

- SFDA’s review procedures for evaluation and registration of food and drugs were tightened, including adopting improved safety controls to verify all the information provided in applications through pharmacological, toxicological and clinical trial analyses.
- The State Council and SFDA launched a campaign to curb corruption and production of counterfeit products within the pharmaceutical industry, with the aim of improving the safety and supply of drugs.
- SFDA started to implement a five-year plan for food and drug safety, with 90% of China’s territory to be covered by a food standards monitoring network by 2010 and the enlargement of drug quality inspection forces. In addition, SFDA personnel involved in food and drug supervision are prohibited

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from owning shares in medical-related companies, collecting lecture fees and receiving expensive gifts. Depending on the severity of the violation, violators may be internally reprimanded, face disciplinary actions or be turned over to judicial authorities.

- SFDA conducted a concentrated review of drug applications submitted prior to October 1, 2007, which included a total of 177,000 prior-approved drug applications and has deregistered some counterfeit drugs.

In connection with the incidents described in this section, we have taken various remedial measures to enhance our corporate governance and internal controls. See “Business — Corporate governance and internal controls” in this prospectus.

### **Other PRC national and provincial level laws and regulations**

We are subject to changing regulation under many other laws and regulations administered by PRC governmental authorities at the national, provincial and city levels, some of which are, or may be, applicable to our business.

Laws regulating medical device manufacturers and hospitals cover a broad array of subjects. For example, regulations control the confidentiality of patient medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We must also comply with numerous additional national and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe we are currently in compliance with these laws and regulations. We cannot assure you that we will not be required to incur significant costs to comply with these laws and regulations in the future or that these laws or regulations or compliance with them will not have a material adverse effect on our business, financial condition and results of operation. Unanticipated changes in existing regulatory requirements or adoption of new requirements could have a material adverse effect on our business, financial condition and results of operation.

### **OTHER REGIONS**

Most major markets have different levels of regulatory requirements for medical devices. Modifications to the approved products require a new regulatory submission in all major markets. The regulatory requirements, and the review time vary significantly from country to country.

You should read the information set forth under “Risk Factors — Risks related to our industry — Our products and facilities are subject to extensive regulation, which may subject us to high compliance costs and expose us to penalties for non-compliance. We may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all.” in this prospectus.