



On behalf of the board (the "Board") of directors (the "Directors") of Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd. (the "Company"), I present the annual report of the Company together with its subsidiaries (collectively as the "Group") for the year ended 31 December 2018 for consideration by the shareholders.

#### **DEVELOPMENT CONCEPTS AND OBJECTIVE**

With the ultimate goal to stay as an innovator and a leader in the bio-pharmaceutical industry, the Group has committed to exploring unmet needs and deficiencies of clinical and patients treatment as well as developing novel and more effective treatments/medicines, so as to realize our mission that "The More We Explore, the Healthier Human Beings Will Be".

Drug procurement with quantity in "4 + 7" cities which was a major milestone has been implemented under the background of pharmaceutical system reform this year. It changed the commercial foundation of the pharmaceutical industry which regarding the development of generic drugs and ME-TOO drugs as kinds of new drugs in the past few decades. In near future, China's medicines will surely be back to the drug pricing model that is internationally accepted, in which prices of new drugs and generic drugs are separately determined. In other words, except those innovative drugs that have been proven specific clinical value, the commercial practice of competitive pricing model will be applied to other drugs, either generic drugs or ME-TOO drugs. In future, we believe that the competition of pharmaceutical enterprises will be reflected in innovation ability and production capacity.

Since its establishment, the Group, as a pharmaceutical enterprise based on drug research and development, has adhered to choosing the projects that can meet the unmet needs and deficiencies of clinical and patients treatment. The evaluation system of the projects process depends on whether specific accomplishment of treatment will be achieved. Such non-commerce opportunities oriented projects-setting policy have brought huge difficulties and challenges to us in the past in China. And the sluggish development of projects was frustrating and the situation that our continued effort cannot be turned into profits was not widely recognized. But we always believe that the real mission of pharmaceutical companies is to develop innovative drugs with clinical value, and Chinese pharmaceutical industry will put this into practice eventually. It was glad to see our mission was reflected on the current changes in the industry. The products launched or under development of the Group have shown positive prospect and the characteristics of not affected by changes of policies. Our effort and strategies adopted over the



years have laid a solid foundation and generated a driving force for the Group's development in the new political environment. Only if we endeavor and continue to optimize our specific strategies for research and development: strengthening our research capacities in the fields where we have leading positions, continually expanding the new clinical indications, adhering to the projects worth spending time with, gradually applying for international drug registration and insisting on terminating the projects that are not in line with the Group's value and make no progress for long term, our products will bring great benefits to the Company while reflecting its value in the future.

# **RESEARCH STRATEGY, REVIEW AND PROSPECTS**

During the year under review, our R&D platforms, namely, genetic engineering, photodynamic-tech, nanotech and oral solid preparation technology, has laid solid foundation for our drug development direction. The Group has committed to developing new clinical indications to tackle selected drugs and developing new medicines and innovative treatments to tackle selected diseases. At the same time, the Group has explored and developed in the fields of molecular targeting, immunotherapy and other fields in order to have a new research and development direction.

During the year under review, with an overall consideration of research resources, risks and cycle time, the Group has continually focused drug development on tumors, skin and self-immunological diseases, reducing the number of innovative drugs, expanding and strengthening the number and progress of commercialized drugs.

#### The projects for innovative research

Such as the research on a new antibody cross-linking drug (ADC) for the treatment of tumors; the research for the treatment of CIN, the research on photodynamic drugs for brain gliomas and bladder cancer; the research on small-molecule drugs for autoimmune diseases; the research on drugs for the treatment of moderate and severe acne, etc. This kind of projects focus on the diseases with unmet needs and the deficiency of clinical and patients treatment. It needs to be further explored due to their uncertainties although they are of great importance in the areas of science and clinical treatment.







#### The projects for international registration and commercialization purpose

Including international registration of listed products, such as the registration as a generic drug in the United States of tumor drug of Doxorubicin Hydrochloride Liposome; the registration as an innovative drug in the United States of Hemoporfin, the first photodynamic drug for the treatment of Port Wine Stain ("PWS") in the world; the commercialization of Nanoparticle Albumin-bound Paclitaxel and the BE study and drug registration of generic drug of obeticholic acid for the indication of biliary cirrhosis, etc. This kind of projects is of specific importance in clinical treatment and has completed the research on technology. Continuously pushing the clinical research and commercialization is the main purpose in our current stage which will expand the number of drugs as well as the production scale and make contribution to the revenue and profit of the Group in short or mid-terms.

Insisting on the research of innovative drugs and strengthening the commercialization development of drugs fully embody the concept of the Group "stand on solid ground and look up at the starry sky". We know that modern medical procedure is implemented jointly by clinicians who perform disease diagnosis based on big data and researchers who continuously explore pathogenesis and innovative therapy or drugs. A real pharmaceutical company should take the responsibility of new drugs development which is the mission of the Company and the significance of its existence. As an R&D company which emphasizes on the research from needs of clinical treatment, our choices face challenges but we never give up. And we also realize that the commercialization of drugs is the basis for the growth of the Company. Only by constantly expanding the Company's product group and maintaining the growth of profits can we expand the Company's scale and make it stable, laying the foundation for further research and development and long-term healthy development of the Group.

In addition, we will try our best to avoid involving in trouble of homoplasy as a result of selecting projects by the use of Chinese method from the drugs or targets which were well-developed overseas. We believe that time will tell, our efforts will be worthwhile both in the areas of clinical treatments for patients and the payback for investors.

#### **GENETIC TECHNICAL PLATFORM**

We will pay constant attention to the ability on building genetic technical platform. We realized that gene technology in terms of signaling pathways control, suppress or strengthen the protein activity, will become the core technology in the area of new drugs development, especially when the research bases on the most fundamental and specific causes and molecular mechanism of diseases. We keep a close eye on hotspots of existing antibody drugs research. We need to find our own direction as the basis of projects selection which means selecting the areas with clinical requirement but lacking effective treatments, with definite positions in scientific theory and unique technology. The Group will continue in making effort on pushing the projects which have entered into clinical trial. We will try to realize the commercialization of protein drugs as early as we can.



The progresses of the projects on genetic technical platform are summarized as follows:

The clinical trial approval for high bio-activity recombinant human TNF receptor (重組親和力TNF受體) for the treatment of arthritis has been obtained in May 2014, and the project has completed clinical trial phase I. The drug is mainly used to treat self-immunological diseases, such as arthritis. Clinical research is terminated due to the consideration of efficacy.



The antibody-drug conjugate drugs have shown obvious advantages on tumor treatment in clinical trials, which is much better than the effect of the conventional antibody plus chemotherapy drugs. In order to follow the development trend in bio-pharmaceutical area, recombinant anti-CD30 human-mouse chimeric monoclonal Antibody-MCC-DM1 injection ("CD30-DM1") for the treatment of tumors has completed pre-clinical study and obtained the clinical trial approval from State Drug Administration during the year under review. For more details, please refer to the indicative announcement of the Company dated 18 July 2018. The Company will carry out relevant clinical research as soon as possible.

Two other antibody-drug conjugate for mammary cancer and gastric cancer has entered into pre-clinical conceptual validation.

Avastin bio-similar drug for the treatment of tumor has obtained clinical trial approval. According to the competitive situation of the target market and the company's existing research strategy, the Company is considering transferring the project to a suitable third party.

#### PHOTODYNAMIC TECHNICAL PLATFORM

The Group has been expanding the drugs development based on photodynamic technical platform. Photodynamic drugs will become the most important product pipeline of the Group. We will continue to exert its feature of "one drug, several indications" and becoming a new scalpel for clinical treatment so that according to the treatment principle of photodynamic drugs, we will design special therapy for some precancerous lesions which cannot be treated or intervened for the moment. The Group is commencing further research on molecular mechanism and their mode of action in order to discover new photodynamic compound to improve the efficacy and overcome the defects. At the same time, exploration of the fundamental research on the relationship between the penetrating power of different light wavelengths and the treatment of tumour is under progress. Meanwhile, we have planned to apply for the international registrations for the launched drugs, which will lay a foundation for the commercialization development of the Group.



The progresses of the projects on photodynamic technical platform are summarized as follows:

As the first commercialization project of the Group, the therapy of Aminolevulinic Acid Hydrochloride combined with photodynamic technology (艾拉®, brand name of the first product) obtained positive market response after it was launched for sale. To expand the application to new indications of this drug is one of the key R&D projects of the Group.

Several years after it was launched to the market, ALA (艾拉®), the first photodynamic drug for the treatment of condyloma acuminate in the world, has become the preferred choice in this area. The therapy of ALA combined with photodynamic technology initiated by the Company was recorded in the text book of Dermatovenercology and relevant clinical treatment guidance



from 2013. The latest nineth edition of Dermatovenercology adds the new application of the aforementioned therapy on the acne treatment, and also includes Hemoporfin developed by the Group as new photosensitizer for the treatment of PWS.

The clinical research progress of Aminolevulinic Acid Hydrochloride used for the treatment of CIN infected by HPV ("CIN") is still slow. Based on the research literature showing good effect, the Company will continue to optimize the clinical trial plan, adhere to the research of this project and strive for early registration of this new indication.

Aminolevulinic Acid Hydrochloride used for the treatment of moderate and severe acne has obtained the clinical trial approval and phase I clinical studies is under way.

Aminolevulinic Acid Hydrochloride used for the adjunctive therapy of brain gliomas has completed pre-clinical study. Considering the market prospects and future capital investment, the Company decided to postpone this project.



FuMeiDa (the brand name of Hemoporfin), the first photodynamic drug for the treatment of PWS in the world, is a new drug with new drug target, new compound and new

indication. During the year under review, FuMeiDa has been launched to the market officially. PWS is the most common congenital vascular malformation characterized by ectatic capillaries in the papillary layer of the dermis. The visible manifestation of this disorder is often considered a disfigurement. The lesions tend to become darker and thicker with time and rarely fade away for life. PWS occurs in anywhere on the body and particularly in face and neck and is reported about 0.3~0.4% incidence of infants worldwide. Before age 40, over 65% of patients without treatment will face the situation of thicken and modular lesions cause great emotional depression. After injection into the blood, Hemoporfin spreads quickly to the surrounding tissues and tends to distribute specifically in vascular endothelial cells. It would selectively damage the photosensitizer-rich vascular endothelium by the use of laser or LEDs with certain wavelength. The dilated and abnormal capillaries in the lesions of patients will be cleared

by photodynamic reaction and further effects of coagulation system. PWS had no good treatment before. As one of the second generation photosensitizer, compared with traditional therapies, Hemoporfin is featured by stable chemical structure, lower photosensitization, rapider metabolism, shorter light-avoidance period requirement, more uniform to treat, higher cure rate, lower incidence of scar formation and lower recurrence rate. The excellent efficacy of the drug in the market and the high



cure rate compared to the traditional laser treatment rejoice the clinicians and researchers. FuMeiDa launched to market in 2017 and clinical trial phase IV is under way. Meanwhile the international registration of this drag was officially launched in 2017. During the year under review, the Group has already made a preliminary communication with the Food and Drug Administration of the United States ("FDA"). We will submit the official application as soon as we optimize the corresponding registration scheme.

Duteroporphyrin (多替泊芬) for the treatment of tumors has entered into the clinical trial phase II. The progress of its clinical trial was slow due to various reasons. Considering the safety and efficacy of the drug, we intend to terminate the clinical research.

#### NANO TECHNICAL PLATFORM

The Group will further develop drugs based on the platform of preparation technology of nano drugs to speed up the ability and the progress of commercialization for the Group.

The progresses of the projects on nano technical platform are summarized as follows:

LIBOd® (里葆多®) for the treatment of tumors, was launched to market in August 2009. The drug is a new doxorubicin formula which adopts the advanced stealth liposomal encapsulation technology and has passive targeting characteristics. It is a new generation of replacement for anthracycline drugs. In oncology, it has the advantages of enhancing efficacy and remarkably lowering the effects of cardiac toxicity, myelosuppression and hair-loss. LIBOd® is used for the treatment of AIDS-relating Kaposi's sarcoma, breast cancer and ovarian cancer. Registration for the drug is being carried out in the U.S.. After the clinical



trial being recognized by FDA, the Company will be required to further obtain the verification of good quality management system of our production plant by FDA before the drug can be launched to the U.S. market.

Vincristine sulphate liposome (LVCR) for the treatment of malignant tumors has completed clinical trial phase I. The Group cautiously decided to transfer this project to an independent third party pharmaceutical company based on the consideration of its future prospect, production conditions and payback period, etc. During the year under review, the transfer agreement is in the execution stage.

Nanoparticle Albumin-bound Paclitaxel (紫杉醇白蛋白納米粒) for the treatment of tumors, has entered into pre-clinical study and some improvements have been made in large-scale production processes. The reform of existing production line for this project has been completed. We will launch the bioequivalence study and then apply for the drug registration.



### ORAL SOLID PREPARATION TECHNICAL PLATFORM

Oral solid preparation is the most basic form of preparation. Both small molecular targeting drugs and special oral preparation are the research fields that new drugs developers pay high attention to. The Company cooperated with other third party research institutions to gradually establish technological systems for such platform in previous years. Various new drugs and generic drugs with specific clinical value are being developed. Oral solid preparation technology is one of the long-term development platforms of the Group.

The progresses of the projects on oral solid preparation technical platform are summarized as follows:

The bioequivalence study of obeticholic acid for hepatobiliary disease has been commenced and we will apply for drug registration as soon as possible. It is a generic drug of a medicine developed in the US and listed worldwide for the treatment of primary biliary cirrhosis (PBC). Such drug has a large market in China which is a country with high incidence of hepatobiliary disease. The Company has engaged a third-party research institution, to break through the patent restrictions on the original drug. The Company was granted the patent in China during year under review.

During year under review, the Group is conducting a pre-clinical study on the selective inhibitor project for JAK1, a small molecular targeting drug. It has been confirmed to have great therapeutic value on the autoimmune disease. We are looking forward to find a new me-better drug containing therapeutic advantages and apply for clinical research as soon as practicable.



### THE EXPLORATION AND DEVELOPMENT OF NEW RESEARCH DIRECTION

New Antigen Vaccine for Cancer: During the year under review, the Group noticed the clinical treatment breakthrough and great potential of personalized tumor vaccine, and conducted in-depth research and exploration in this direction. The Group has jointly carried out immunotherapy based on neo-tumor antigen with hospitals and research institutes for a number of patients. The Group will continue to maintain the attention in this direction and seek cooperation opportunity with foreign research institutions for a suitable entry point of the Group.

By the end of the year 2018, the major drugs under R&D of the Group are summarized as follows:

Technical platform	Project name	Indications	Progress
Genetic engineering	rhTNFR(m):Fc (High bio-activity recombinant human TNF receptor 2-Fc fusion protein mutant (高活性重組人腫瘤壞死因子受體突變體-Fc融合蛋白)	Arthritis	Clinical trial phase I completed. Terminated due to effectiveness problems.
	CD30-MMAE	Tumors	The clinical trial approval has been obtained.
	Trop 2 Antibody-drug conjugates	Tumors	Pre-clinical study
	Avastin	Tumors	The clinical trial approval has been obtained. Negotiating with third-party pharmaceutical enterprises on technology transfer.
Photodynamic technology	Hemoporfin (海姆泊芬)	Port Wine Stain	Clinical trial phase IV  Prepare for U.S. Registration
	Deuteroporphyrin (多替泊芬)	Tumors	Clinical trial phase II. Terminated due to safety and effectiveness problems.
	Aminolevulinic acid	Cervical diseases infected by HPV	Clinical trial phase II
	Aminolevulinic acid	Acne	Clinical trial phase I
	Aminolevulinic acid	Brain gliomas	Pre-clinical study completed
Nano technology	Doxorubicin liposome (鹽酸多柔比星 脂質體)	Tumors	Under process of registration in USA
	Nanoparticle Albumin-bound Paclitaxel (紫杉醇白蛋白納米粒)	Tumors	Pre-clinical study
Oral solid preparation technology	Obeticholic acid	Hepatobiliary disease	BE study and drug registration
	JAK1 inhibitor	Autoimmune diseases	Pre-clinical study



In a word, we are still exploring and hope our efforts can provide useful help for the treatment of the patients and bring value to the investors. Although facing significant risks and challenges, we still believe our R&D strategy and result will be beneficial to the Company's sustainable development in medium and long term.

# **OPERATION STRATEGY, REVIEW AND PROSPECTS**

The Group's operating strategy is to do a good job of domestic academic promotion of listed products, so that products can be applied among more patients. When conditions are ripe, international (mainly European and the United States) registration of listed products should be carried out as soon as possible to benefit more patients and obtain greater therapeutic value and commercial benefits. Secondly, China has joined the ICH Organization, which lays the foundation for the internationalization of research. Therefore, the medium and long-term research projects being developed by the Group must be able to register at home and abroad (such as the United States) in order to achieve the goal of the internationalization of the long-term development of the Group. Finally, we need to pay close attention to the selection and development of foreign investment projects, in order to balance the short-term and long-term development plans of the Group, and ultimately achieve the goal of the development of the Group and the realization of shareholders' benefit.

During the year under review, product sales revenue of the Group increased by 49% compared with that of last year. ALA ( $\mbox{$\dot{Z}$}$  which is indicated for the treatment of dermal HPV infectious disease and proliferative disease, LIBOd® which is indicated for the treatment of tumor and FuMeiDa which is indicated for PWS are three major products of the Group, and together contributed 99% of the sales revenue of medical products by the Group.

- ALA (艾拉®) was launched in the market in 2007. As the first photodynamic drug in China, ALA can selectively spread and accumulate in condyloma acuminatum cells, and kill them together with specific wavelength light and energy, which does not result in adverse effects on surrounding normal tissues at the same time. Due to the feature of this therapy, ALA also has effects on the treatment of subclinical infection and latent infection. Compared with traditional therapy, the therapy of ALA combined with photodynamic technology, filled in the blanks in the treatment of urethral orifice condyloma acuminate. In addition, our therapy has the advantages such as better tolerance of patient, higher safety, non-scar, and



much lower adverse reaction rate and recurrence rate comparing with previous average level. ALA has become one of the largest consumed skin-sure drugs now. During the year under review, the contribution of ALA to sales revenue of the Group increased by 29% compared with that of last year due to sales strategy adjustments based on market trends. The sales volume of ALA grew steadily and average unit price increased slightly.



LIBOd® (里葆多®) for the treatment of tumors, as the first generic drug of nanomedicine at home and abroad, was launched for sale in August 2009 and it obtained favorable market response and reputation. During the year under review, the Company established a new sales and marketing team for responding the sales and promotion of LIBOd® nationwide. Its terminal sales gradually recovered so that its contribution to sales revenue by the Group increased by 89% for the year 2018 compared with that of last year. With the gradual implementation of the "two invoice" system, and affected by the change of national policies and the industry environment, the market competition of doxorubicin liposome tends to be more fierce. As the increase in the market shares of LIBOd® of the Company needs a large-scale oncology drug promotion team as the basis, the Company needs a long time to build its own promotion team and achieve ideal promotion performance. In order to accelerate the expansion on market share of LIBOd® as well as meet high standards of compliance requirements, on 29 October 2018, the Company and Huizheng (Shanghai) Pharmaceuticals Technology Co., Ltd.\* (輝正(上海)醫藥科技有限公司) ("Shanghai Huizheng") entered into the market promotion service agreement for Doxorubicin liposome (LIBOd®) (the "Agreement"), to provide the market promotion services for LIBOd® of the Company in the PRC from 1 November 2018. Shanghai Huizheng, a subsidiary of Zhejiang Haizheng Pharmaceutical Co., Ltd., a company listed on the Shanghai Stock Exchange (Stock Code: 600267), owned a oncology drug promotion team with several hundred professional promotion personnel as well as a large number of counterpart hospitals and medical resources. The cooperation between the parties will help the Company effectively utilize the existing team and resources of Shanghai Huizheng, thus rapidly increasing the end-sales volume and market shares of LIBOd® of the Company. Meanwhile, to ensure the smooth transition of relevant businesses, the original promotion team of the Company will be fully integrated with the promotion team of Shanghai Huizheng. For more details, please refer to the announcement of the Company dated 29 October 2018.

The Group is currently registering for generic drugs of LIBOd® in the United States.

# - 复美达光动力



FuMeiDa (复美达®, the brand name of Hemoporfin), the first photodynamic drug for the treatment of PWS in the world, is a new drug with new drug target, new compound and new indication. FuMeiDa has been launched in the market officially in 2017. We have designed a new sales mode for FuMeiDa, with the integration of treatment and sales, which includes

the Company's Wechat subscription, chain clinics of the Group, designated hospitals and direct distribution systems provided by pharmaceutical companies. During the year under review, FuMeiDa has been sold in many hospitals throughout the country with well postoperative feedback and its contribution to sales revenue of the Group increased by 80% compared with that of last year. The Group is combining case feedback as soon as possible to optimize the key steps in the process of treatment in order to form a standardized treatment plan.

The group has completed preliminary communication with the FDA during the year under review, and the FDA has recognized that the drug will be the first one to apply for the treatment of PWS. Therefore, the Group was requested to assist in establishing standards for disease classification and then to make agreement with the FDA. At the same time, the clinical research program registered in the United States has been clarified. At present, the Group is working hard to complete the preparations before the official clinical application. After the corresponding registration program is improved, clinical research in the United States will be carried out as soon as possible.



For the past years, as the first product group, diagnostic reagents in clinical treatment contribute stable sales revenue to the Group. With intensive competitions in diagnostic technology industry, the advantages of this product group became weaker and weaker and there are few good reserve projects. In order to further strengthen diagnostics business unit and integrate in existing vitro diagnostic reagents platform, the Group invested to set up the subsidiary, Tracing Biotechnology jointly with a third party investor in 2012 and the new company covers all sectors including R&D, production and sales of the diagnostic reagents. In addition, during the year of 2015, the Group completed a series of jobs on structure restructuring and resource integration of this platform so that we can improve the competitiveness of diagnostic products and develop more and more new products.

During the year under review, the Group keeps increasing investments on diagnosis technique and reagent research, and planned to push the "rapid, quantitative detection system" as starting point of entering into clinical medical market to develop the molecular diagnostic technique based on the technology of adapter body as technical reserves. This platform will focus on the specialized market of grassroots medical, obstetrics and neonatal unit, which can become the significant component of the industry layout of the Group in the area of diagnosis technology.

After the integration of vitro diagnostic reagents platform, the Group clarified the establishment of food-origined contaminants screening system as our direction of development in the area of clinical detecting besides keeping exploring the existing dairy tests market. The Group will provide solutions for rapid screening, timely intervention and source control after focusing on food-origined contaminants such as antibiotics and mycotoxins in the early stage of human being. During the year under review, several kinds of screening reagents for food-origined antibiotics and their matching testing instruments have been applied for registration and obtained approval for sale in March 2019.

During the year under review, the Group continues to regard academic promotion as our primary marketing method.
 The Wechat communication platform for photodynamic technology that the Company established serves as a network service system integrated with academic exchanging among dermatology clinician, sharing of clinical case and standard

practice video, Q&A platform between doctors and patients, etc. The platform has become a relatively well-known professional Wechat subscription in China. In addition, we plan to take advantage of these doctor resources on the platform to develop a new sale mode to solve some frequent problems in current marketing environment and some frequent difficulties for patients in hospital. We believe this kind of investment will have positive significance for products promotion, brand awareness and the Company's recognition as well.





Making full use of the advantages accumulated in skin management field these years, the Group invested in the establishment of Derma Clinic Investment Co., Ltd.\*(德美診聯醫療投資管理有限公司)("Derma Clinic") in August 2015. During the year under review, nine clinics invested and set up by Derma Clinic in Beijing, Chongqing, Changsha and Shenzhen etc., have all completed relevant registration procedures and opened for business. In recent years, with the vigorous development of the domestic medical and aesthetic industry, the influx of various funds has also led to the uneven quality of the entire industry. As an enterprise taking research and development of drugs as its principal business, the Company, after completing the initial framework design, corporate strategy formulation and development direction planning for Derma Clinic, considers that it is necessary to involve a shareholder who is familiar with specific industry business, capable of effective resources integration and equipped with relevant industry experience and management experience of chain enterprises to lead and guide the subsequent development direction of Derma Clinic so as to enhance the overall operation of Derma Clinic. In this situation, in order to focus on the core business of the Group, during the year under review, the Group began to seek strategic partners who are familiar with the industry business, capable of effective resources integration, and able to guide the development of Derma Clinic. On 28 February 2019, the Company entered into an equity acquisition agreement with Shenyang Bringspring-Roadtop Health Data Industrial Equity Investment LLP. (瀋陽榮科融拓健康數據產業股權投資合夥企業(有限合夥)) ("Bringspring-Roadtop") to sell 30.04% of equity interest in Derma Clinic. Upon the completion of the transfer, Bringspring-Roadtop will own 63% of equity interest in Derma Clinic while the Company will own 20% of equity interest in Derma Clinic. Therefore, Derma Clinic will cease to be a subsidiary of the Company, and its financial results will not be consolidated into the consolidated financial statements of the Company. For more details, please refer to the announcement of the Company dated 28 February 2019. In the future, the Group will continue to cooperate with Derma Clinic as new marketing channels and clinical treatment platforms for new photodynamic drugs.

During the year under review, all the product lines for existing products in sale of the Group passed GMP Certification of China Food and Drug Administration. Our objective is to set up the product lines which can meet international standard so that our products could be sold worldwide. The management has considered to apply the GMP certification of FDA to two product lines in Shanghai and Taizhou. In the future, the timetable will be made according to specific commercialization projects.

The subsidiary of the Company, Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd ("Taizhou Pharmaceutical") has constructed two production lines for the material and injection of Hemoporfin. To make the two production lines at full capacity before further new self-developed innovative drugs obtaining production approval, the Group will choose several generic drugs which can be produced with Hemoporfin on the same production line and planned to submit the application of registration. The work of technology research of these generic drugs has been completed and the registration will be applied for according to the production plan of the production line. The registration application of Parecoxib Sodium (帕瑞昔布鈉) for analgesia has been submitted and waiting for approval during the year under review. In addition, Taizhou Pharmaceutical has built a new solid preparation production line during the year under review, which is ready for the commercialization of obeicholic acid. More investments on production lines will be made in Taizhou in the next few years so as to make Taizhou Pharmaceutical become the centralized production base of the Group.

The Group has successfully accomplished the transformation from purely R&D to equally stress on both R&D and commercialization with a complete system featuring organic combination of R&D, product manufacturing and marketing. The Group is moving toward a virtuous stage of development.



By the end of the year 2018, the commercialized projects of the Group are summarized as follows:

Technical platform	Project name	Indications	Launching time
Photodynamic technique	ALA	Condyloma acuminate	2007
	FuMeiDa	Port wine stain	2017
Nano technique	LIBOd®	Tumors	2009
Diagnosis and Inspection	Antenatal screening diagnostic reagent, analysis software and equipment including	Down's syndrome	Launched already
	Beixi®, Beiyou Several food safety inspection projects	food safety inspection	Launched already

## **INTELLECTUAL PROPERTY RIGHTS**

The Group has been actively protecting its intellectual property rights on its innovative medicines and research achievements. During the year under review, the Group applied for 3 invention patents, and has been granted 4 invention patents in domestic. By the end of the year of 2018, the Group has cumulatively applied for 75 invention patents, and has been granted 46 invention patents.

### **GRANTS AND AWARDS**

The Group has always been improving its ability of new drugs development in light of the industrial policies of China. During the year under review, the grants and awards obtained by the Group from governments at all levels for a number of R&D and commercialization projects approximately amounted to RMB22,846,000.

#### **ACKNOWLEDGEMENT**

Lastly, I would like to take this opportunity to express my gratitude to the shareholders and business partners of the Group for all their unreserved support and encouragement. I would also like to express my most sincere thanks to all the Directors, Supervisors and all the staff of the Group for their dedication and contribution.

#### Wang Hai Bo

Chairman

Shanghai, the PRC 28 February 2018