CHINA PHARMA HOLDINGS, INC.
Form 10-K
March 28, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

or

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-34471

China Pharma Holdings, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**73-1564807**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*

Second Floor, No. 17, Jinpan Road

Haikou, Hainan Province, China 570216

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number: **(011) 86 898-6681-1730**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 Par Value Per Share	NYSE American

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s)), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $5,327,719 as of June 29, 2018, based on the closing price of $0.22 of the Company's common stock on such date.

The number of outstanding shares of the registrant's common stock on March 26, 2019, was 43,579,557.

Documents Incorporated by Reference: None.

FORM 10-K ANNUAL REPORT

FISCAL YEAR ENDED DECEMBER 31, 2018

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FORWARD-LOOKING STATEMENTS

The statements contained in this report with respect to our financial condition, results of operations and business that are not historical facts are “forward-looking statements”. Forward-looking statements can be identified by the use of forward-looking terminology, such as “anticipate”, “believe”, “expect”, “plan”, “intend”, “seek”, “estimate”, “project”, “could” the negative thereof or other variations thereon, or by discussions of strategy that involve risks and uncertainties. Management wishes to caution the reader of the forward-looking statements that any such statements that are contained in this report reflect our current beliefs with respect to future events and involve known and unknown risks, uncertainties and other factors, including, but not limited to, economic, competitive, regulatory, technological, key employees, and general business factors affecting our operations, markets, growth, services, products, licenses and other factors, some of which are described in this report including in “Risk Factors” in Item 1A and some of which are discussed in our other filings with the SEC. These forward-looking statements are only estimates or predictions. No assurances can be given regarding the achievement of future results, as actual results may differ materially as a result of risks facing our company, and actual events may differ from the assumptions underlying the statements that have been made regarding anticipated events.

These risk factors should be considered in connection with any subsequent written or oral forward-looking statements that we or persons acting on our behalf may issue. All written and oral forward looking statements made in connection with this report that are attributable to our company or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Given these uncertainties, we caution investors not to unduly rely on our forward-looking statements. We do not undertake any obligation to review or confirm analysts’ expectations or estimates or to release publicly any revisions to any forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

Notwithstanding the above, Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) expressly state that the safe harbor for forward-looking statements does not apply to companies that issue penny stock. If we are ever considered to be an issuer of penny stock, the safe harbor for forward-looking statements may not apply to us at certain times.

PART I

ITEM 1. BUSINESS

Overview

We are principally engaged in the development, manufacture and marketing of pharmaceutical products for human use in connection with a variety of high-incidence and high-mortality diseases and medical conditions prevalent in the People's Republic of China (the "PRC"). All of our operations are conducted in the PRC, where our manufacturing facilities are located. We manufacture pharmaceutical products in the form of dry powder injectables, liquid injectables, tablets, capsules, and cephalosporin oral solutions. The majority of our pharmaceutical products are sold on a prescription basis and all have been approved for at least one or more therapeutic indications by the China Food and Drug Administration (the "CFDA") based upon demonstrated safety and efficacy.

As of December 31, 2018, we manufactured 19 pharmaceutical products for a wide variety of diseases and medical indications, each of which may be classified into one of three general categories:

- Basic generic drugs, which are common drugs in the PRC for which there is a very large market demand;
- First-to-market generic drugs, which are generic Western drugs that are new to the PRC marketplace; or
- Modern Traditional Chinese Medicines, which are generally comprised of non-synthetic, plant-based medicinal compounds of the type that have been widely used in the PRC for thousands of years, to which we apply modern production techniques to produce pharmaceutical products in different formulations, such as tablets, capsules or powders.

In selecting generic drugs to develop and manufacture, we consider several factors, including the number of other manufacturers currently producing a particular drug, the size of the market for that drug, the proposed or required method of distribution, the existing and expected pricing for that particular drug in the marketplace, the costs of manufacturing that drug, and the costs of acquiring or developing the formula for that drug. We believe we have historically selected generic drugs for manufacture that have large addressable markets and higher profit margins relative to other generic drugs manufactured and distributed in the PRC.

We currently own and operate an approximately 8,000-square-meter manufacturing facility in Haikou, Hainan Province, built in 2002, that supports eight modern, scalable production lines. We implement quality control procedures in this facility in compliance with the PRC's Good Manufacturing Practices, or GMP standards, and applicable CFDA regulations to ensure consistent quality in our products.

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The CFDA promulgated *Good Manufacturing Practices for Pharmaceutical Products* (2010 revised version) (the "new GMP") on February 12, 2011 (effective as of March 1, 2011). The new GMP standards outline the basic principles and standards for the manufacturing of pharmaceutical products and the management of quality controls in the pharmaceutical products manufacturing industry in the PRC. Pursuant to those mandatory requirements, upgrades to our two injectables production lines were required to be finalized by the end of 2013. From January 1, 2014 to November 3, 2014, we suspended production at our dry powder injectables and liquid injectables production lines due to a failure to meet the new GMP upgrade deadline. However, in 2014, we completed construction of a new 20,000 square-meter factory equipped with four sterilized production lines (two liquid injectables and two dry powder injectables production lines), in full compliance with the latest GMP standard. In November 2014, the CFDA completed GMP certification of our new facility and issued us a GMP certificate, enabling us to commence manufacturing at our two liquid injectables and two dry powder injectables production lines. In January and December 2015, we completed further upgrades and received new GMP certificates for the tablet and capsule production lines and the cephalosporin production lines in our old factories.

We market and sell our products through 16 sales offices covering all major cities and provinces in the PRC. To comply with applicable Chinese law relating to sales of prescription drugs to certain hospitals and clinics, we also use a distribution system comprised of over 1,000 independent prefecture-level, city-level, and county-level distributors. Our sales system has further developed and expanded with the expansion of Chinese healthcare reform, and our 16 provincial offices deliver our products to basic health care institutions as well as tier two and tier three hospitals through the above mentioned distributors.

Corporate History

We are a holding company and conduct substantially all of our production, marketing, finance, development and administrative activities through our wholly-owned subsidiary located in the PRC. We were incorporated in the State of Delaware under the name "Softstone, Inc." on January 28, 1999. From mid-2003 to October 19, 2005, we did not generate any significant revenue and we accumulated no significant assets while we explored business opportunities as a publicly-held "shell" corporation.

We entered into our current line of business on October 19, 2005, through the acquisition of Onny Investment Limited, a holding company formed in the British Virgin Islands ("Onny"), and its operating subsidiary located in the PRC, Hainan Helpson Medical & Biotechnology Co., Ltd. ("Helpson"). On March 16, 2006, we changed our corporate name to China Pharma Holdings, Inc. On December 31, 2012, we reincorporated from the State of Delaware to the State of Nevada.

Helpson was established on February 25, 1993, in Haikou, Hainan Province, PRC as a foreign-invested enterprise. The company was originally an "equity joint venture," as defined by China's laws on foreign invested enterprises, between Haikou Biomedical Engineering Co., Ltd., a PRC company, and Hong Kong Fudao Development Co., Ltd., a Hong Kong company ("Fudao").

On June 16, 2001, Fudao entered into an Equity Interest Transfer Agreement with Hainan Kaidi Science and Technology Co., Ltd., a PRC company ("Kaidi"), pursuant to which Fudao transferred all of its ownership interest in Helpson to Kaidi. As a result of this transfer, Helpson became a PRC domestic company, rather than a foreign-invested company.

Onny was incorporated on January 12, 2005, under the laws of the British Virgin Islands. On May 25, 2005, Helpson's three then-existing shareholders entered into an equity interest transfer agreement with Onny, as a result of which, effective as of June 21, 2005, Helpson became a wholly foreign-owned enterprise ("WFOE"), and Onny became the sole shareholder of Helpson.

On October 19, 2005, we acquired all of the issued and outstanding shares of Onny in exchange for 27,499,940 shares of our common stock and became Onny's sole shareholder. In connection with this share exchange, all of our officers and directors at that time resigned from their positions as officers and directors of our Company, and new directors and executive officers were appointed. Also as a result of this share exchange, commonly referred to as a "reverse acquisition," Helpson became our indirect wholly-owned subsidiary.

Our corporate organizational chart is set forth below.

Industry Background and Market Opportunities

According to data provided by the National Bureau of Statistics of China, business income of pharmaceutical manufacturers above the designated size (i.e., manufacturers with annual production of a minimum of RMB20 million, or approximately $2.98 million) reached CNY2426.47 billion in 2018, which represented an increase of 12.4% over the same period of last year. Among these manufacturers, the main business income was CNY2,398.63 billion (approximately USD357.40 billion), which represented an increase of 12.6% over the same period last year, an increase of 0.1 percentage points over the previous year, which was 4.1% higher than the overall level of industrial enterprises above designated size in the same period. Total profit reached CNY309.42 billion (approximately USD46.10 billion), an increase of 9.5% over the same period last year. Profit margin of the main business of pharmaceutical manufacturing industry is 12.90%, which is 1.14% higher than the same period last year, and 6.41% higher than the overall level of Industrial Enterprises above designated size in the same period.

In 2018, Comprehensive institutional reforms were implemented, and major changes have taken place in the medical and health functional departments, including the establishment of the National Health and Health Commission, the discontinuation of the National Health and Family Planning Commission, the establishment of the National Medical Security Bureau, and the establishment of the National Drug Administration. These reforms focus on the optimization and adjustment of institutional functions in the fields of medical care, medical insurance, medicine and key links, which is conducive to improving the efficiency and effectiveness of administration and supervision and deepening the medical reform.

In terms of changes to medical policy in 2018, the Chinese Health and Health Commission adjusted the national Essential Drug List with an increased number of enrolled drugs, improved the structure of included drugs, and added emphasis on the basic drugs demand for common and chronic diseases on one hand; and carried out many regulations and reforms in order to promote the construction of the graded diagnosis and treatment system, established and improved the modern hospital management system, and strengthened the management of supplemental drugs and clinical pathways on the other hand. In terms of health insurance policy, the State Medical Insurance Bureau has incorporated 17 anticancer drugs into the national health insurance through negotiations; organized a pilot scheme for centralized drug purchases, and explored the improvement of centralized drug procurement and market-led drug pricing mechanisms. In terms of pharmaceutical policy, the Chinese State Administration of Pharmaceutical Supervision has optimized the process of drug registration, examination and approval, accelerated the speed of import drug registration, encouraged Chinese enterprises to go out and carry out global synchronous clinical research and development, continued to promote the evaluation of the consistency evaluation to guarantee the safety and effectiveness of generics, and promoted the upgrading and structural adjustment of the pharmaceutical industry.

We have observed that the prices of pharmaceutical finished products have been declining while the prices of raw and auxiliary materials have generally increased. Due to strengthened environmental protection, many raw material enterprises have been forced out of business. In addition, some enterprises monopolize the production and sale of certain raw materials, which leads to soaring prices.

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It has been difficult for the chemical drug industry to maintain the same high growth rate it experienced before 2012 due to the completion of the expansion of health insurance, with the positive impacts of its policies' gradual declines, as well as the existence of Medicare cost-controls and drug pricing pressures resulting from drug bidding. However, in the context of China's aging population, the consumption of pharmaceuticals is expected to increase, and although the growth rate of health insurance expenditures will not remain at the previous high level, the industry will still be able to maintain growth. In addition, personal expenditures and public finance expenditures in healthcare are expected to continue to increase. Therefore, we believe that demand for pharmaceuticals and the consumer's ability to pay is still enjoying steady growth. Although the growth rate has been declined, the scale of pharmaceutical industry in China is still huge.

Consistency Evaluation

The development of generic drugs is an important measure to reduce medical expenses. By conducting generic drug consistency evaluations, generic drugs can be advertised as consistent with the original drug in terms of efficacy and quality, and may even replace the original drug in clinical practice. This work can greatly enhance the overall development of China's pharmaceutical industry, and it also provides support for the quality of generic drugs.

The Chinese State Drug Administration issued a Notice on Consistency Assessment of Quality and Efficacy of Generic Drugs (hereinafter referred to as the Notice) on December 28, 2018. The Notice points out that the National Essential Medicines Catalogue (2018 edition) (hereinafter referred to as the New Edition Catalogue) has been put into effect as of November 1, 2018. The New Edition Catalogue has established a dynamic adjustment mechanism, giving priority to the formulas that pass the consistency evaluation, gradually transferring formulas that fail to pass the consistency evaluation out of the Catalogue. Due to the importance of ensuring the clinical needs of essential drugs, the time limit for evaluating essential drugs is no longer set uniformly for the drugs included in the national Essential Drugs Catalogue.

This does not mean that the time limit requirement for the evaluation of essential drugs has been eliminated. The Notice also pointed out that generic drugs, including essential drugs, which were approved for market before the implementation of the new registered classification of chemicals, should, in principle, complete the consistency evaluation of the same formula of other pharmaceutical manufacturers within three years after the first applicant passed the consistency evaluation. If an enterprise fails to complete the evaluation, it may apply to the local provincial drug regulatory authorities for postponement of the evaluation if it considers that the drug in question is both clinically necessary and in short supply in the market. After being confirmed by the provincial drug regulatory authorities in conjunction with the health administrative departments, the applicant may appropriately postpone the evaluation.

Our company has actively promoted the consistency evaluation process of several key current existing oral products in 2018.

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On March 5, 2016, the Chinese State Council issued “Opinions on Carrying out Consistency Evaluations of the Quality and Efficacy of Generic Drugs” (the “Opinions”). Over 95% of the currently-sold drugs in China are generics which are subject to the “Opinions”. Per the “Opinions”, any solid oral solution generics listed in the National Essential Drugs List (2012 edition) that received production approval before October 1, 2007, shall complete a Consistency Evaluation by the end of 2018,while an applicant which needs to carry out clinical trials and has certain special circumstances shall complete a Consistency Evaluation by the end of 2021. Overdue applicants may no longer be eligible for re-registration. According to CFDA statistics, a total of 289 formulas, 17,740 production approval numbers, 1,817 domestic pharmaceutical manufacturers, and 42 overseas manufacturers will be affected by the Opinions. Unfortunately, annual sales of most of those 17,740 production approval numbers did not exceed RMB5 million, in which case, manufacturers may wait an extended period of time to recoup their capital investment for consistency evaluations. The similarities in the pharmaceutical market in China lead to low profit rate. The money invested in consistency evaluations comes from the manufacturer; therefore in general, manufacturers prefer to take consistency evaluations of selected existing products with higher profitability.

The Oral Solid Formulation Conformance Assessment 289 catalog has more than 18,000 drug approvals. The annual sales of most varieties do not exceed 5 million. It takes an extended period of time for companies to recoup the cost of consistency assessment.

In order to promote consistency evaluations, the P.R.C. State Council and its related agencies have issued corresponding policies. The result is two core points: first, the medicines that pass the consistency evaluation are given appropriate support in coverage by health insurance; and should be given priority during drug purchase and prescription; the second applies when more than 3 manufacturers have passed the consistency evaluation for a certain drug, then other manufacturers will no longer be eligible to participate in centralized purchase for this drug.

Consistency evaluations have resulted in a reshuffle of the generic pharmaceutical industry. Generic drugs whose quality levels are not up to standard will be withdrawn from the market. The revision of the national drug standards can be seen as a continuation of this policy and will intensify the shuffling of the pharmaceutical industry.

There were 149 consistency evaluation tasks (according to acceptance number) published by Center for Drug Evaluation (CDE), involving 74 formulas and 75 enterprises as of May 15, 2018. And 35 of these 149 acceptance numbers have been approved (29 of them have been published by CFDA), 38 have been required for supplements, 3 have been rejected, and 73 have been under review.

Bioequivalent Testing costs are considered a major share in the overall costs of Consistency Evaluations, which in turn will increase capital expenditures for our industry. In addition, if a generic drug under evaluation cannot achieve the same consistency of quality and efficacy as the originally-developed drug, the generic manufacturer must re-develop and optimize its existing formula and production process through further analysis of the quality standards and physical and chemical characteristics of the originally-developed drug, including a study of the crystal form and solubility.

The Center for Drug Evaluation released the "Technical Requirement for the Consistency Evaluation of Marketed Chemicals (Injectables) (Draft for Comment)" on December 22, 2017, which launched a prelude to the consistency evaluation of injectables. According to the statistics of Pharmaceutical Intelligence Drug Registration and Acceptance Database, as of January 15, 2019, CDE has accepted 155 applications of consistency acceptance numbers for injectables from 66 pharmaceutical companies with regards to 43 formulas.

The PRC's medical insurance system

The Chinese National Medical Insurance Bureau was officially established on May 31, 2018. The reform has given the Medical Insurance Bureau great functions and powers. After the establishment of the Medical Insurance Bureau, it will become a centralized department with the power of overall decision and a decision-maker with the greatest voice in drug procurement, medical service evaluations, and the medical insurance payment system. The newly established Medical Insurance Bureau has reorganized the functions previously dispersed in four ministries: basic medical insurance and maternity insurance for urban workers and residents of the Ministry of Human Resources and Social Affairs, the New Agricultural Cooperation of the State Health and Planning Commission, the price management of drugs and medical services of the National Development and Reform Commission, and the medical assistance responsibilities of the Ministry of Civil Affairs. This reorganization has broken down the restrictions on the functions of the original ministries and commissions, thoroughly restructured the previous operations of the pharmaceutical products, medical insurance and medical treatment division, and reshaped the functions of medical procurement and medical service supervision within the scope of medical insurance, so that the follow-up medical reform has a clearer direction and stronger execution. As a "super buyer" integrating purchasing power, pricing power and payment power, the newly established National Medical Insurance Bureau will be more prominent in the implementation process of subsequent collection and payment of medical insurance.

The cumulative income of the basic medical insurance fund was RMB18.63 billion during January to November 2018, an increase of 14.9% compared with the same period last year. And the cumulative expenditure was RMB1.475 billion, an increase of 19.9% compared with the same period last year. This showed that the expenditure side has not declined obviously due to drug-fees-control, but reflected the government orientation of "the goal of the medical insurance bureau is not only to control fees, but also to expand coverage". The number of basic medical insurance coverage has reached 1.21 billion by the end of November 2018 in China, which represented an increase of 5.3% over the same period last year. The number of insured persons is continuously increasing driven by the implementation of the policy of "two-in-one insurance".

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The direction of reform of China's medical insurance payment method has been established. As such, the total amount of medical insurance expenditures is controlled through the mixed payment methods such as total advance payment and disease-based payment. At the same time, the drugs with clinically urgent needs and high degrees of innovation are included in the scope of reimbursement through price negotiation. The drugs that solve the medical problems of part of the patients with major diseases help reduce or even eliminate the proportion of reimbursement for supplemental medicines; thus, allowing the remaining medical insurance funds to be used for innovative drugs and high-quality generic drugs with therapeutic effects.

Our Strategy

We believe that in the pursuit of innovative research and development is imperative for providing the basic medical solutions needed by the majority of patients. We are passionate about protecting human health, and always adhere to the highest standards of ethics and integrity, fulfilling our firm commitment to our customers and patients.

We believe we are well-positioned in a comparatively steadily growing industry in one of the fastest-growing economies in the world. We currently manufacture a number of off-patent branded generic drugs that were among the first to market in the PRC. We expect to continue to gain additional competitive advantages through the growing pipeline of new pharmaceutical products we are developing for specific target patient groups. Our diverse portfolio of products and our new product pipelines include products for high-incidence and high-mortality conditions in the PRC, such as cardiovascular, central nervous system ("CNS"), infectious, and digestive diseases. Furthermore, the Healthcare Reform initiated by the State Council in 2008 in the PRC has significantly expanded the landscape of the Chinese healthcare industry.

Based on our experience in R&D, production and marketing of specialized pharmaceutical products in China for more than 20 years, and our market insights, we have decided to gradually adjust our strategy to produce generic and innovative drugs with high value in pharmacoeconomics, good clinical efficacy and market differentiation. These include drugs for the treatment of chronic diseases prevalent in China, geriatric diseases, cancers, and nutritional products.

Overall, the development of China's pharmaceutical industry has been good in 2018. The main indicators are showing improvement in varying degrees. The "One Belt One Road" initiative has been heavily promoted, the 2030 Healthy China plan has been fully implemented, international demand has been growing, and the rate of domestic health consumption has been accelerated. However, the pharmaceutical industry is still in need of strengthened policy and financial supports through multiple channels to improve the drug supply mechanism, enhance industry concentration and internationalization levels.

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Our objective is to leverage our expertise in the PRC for the development, manufacture and commercialization of pharmaceutical products. We intend to achieve this objective by:

Promoting Our Existing Brands to Increase Our National Recognition. We intend to support and grow the existing recognition and reputation of our brands and to maintain our branded pricing strategy through continued sales and marketing efforts through our new, upgraded GMP-compliant production lines. To achieve this goal, we plan to promote the efficacy and safety profile of our established prescription pharmaceutical products to physicians at hospitals and clinics in all provinces of PRC through the efforts of our sales force, independent distributors and educational physician conferences and seminars.

Developing and Introducing Additional Products to Expand or Strengthen Our Existing Product Portfolio. We plan to focus our development capabilities towards expanding our existing portfolio of approved products. We have a number of products in various stages of the CFDA approval process. In addition, we intend to conduct clinical trials for new generic or modernized products to expand our existing product portfolio. We plan to introduce new generic or modernized products to leverage our branded market leadership position, particularly in therapeutic areas in which we already have a strong presence.

Expanding Our Distribution Network to Increase Market Penetration. We intend to expand our reach beyond our current 16 offices in the PRC to drive additional growth of our existing and future products. We currently contract with over 1,000 distributors in the PRC and plan to expand on these relationships to target new markets. We will continue our conservative sales strategy of increased cooperation with customers with reliable accounts receivable collection performance. In addition, we plan to continue to broaden our marketing efforts outside of major cities in the PRC and to increase our market penetration in cities and rural areas where we already have a presence. Over the long term, we also intend to expand our presence beyond the PRC to international markets by working with international pharmaceutical companies in cross-selling our products.

Acquiring Complementary Products Lines, Technologies, Distribution Networks and Companies. We intend to selectively pursue strategic acquisition opportunities that we believe will grow our customer base, expand our product lines and distribution network, enhance our manufacturing and technical expertise or otherwise complement our business or further our strategic goals. Pursuing strategic acquisitions is a significant component of our growth strategy. The Company has not identified any strategic acquisition opportunities as of the date of this report on Form 10-K.

Products

We currently have a product portfolio of 19 pharmaceutical products that address a wide variety of diseases and medical indications. All of our pharmaceutical products have demonstrated safety and efficacy in clinical trials sufficient to obtain approval by the CFDA and are sold on a prescription basis. The following table summarizes the approved indications for our marketed pharmaceutical products and the year in which each of such products was first marketed to our customers.

Product	Indication	Year of Commercial Launch
Central Nervous System (CNS) and Cerebral-Cardiovascular Diseases		
CerebroproteinHydroloysate Injection	Memory decline and attention deficit disorder caused by the sequela of craniocerebral trauma and cerebrovascular diseases.	1996
Gastrodin Injection	Tiredness, loss of concentration, poor sleep, and traumatic syndromes of the brain, including vertigo, neuralgia and headaches.	2005
Propylgallate for Injection	Cerebral thrombosis, coronary heart disease and complications after surgery such as thrombus deep phlebitis.	2006
Ozagrel Sodium for Injection	Acute thrombotic cerebral infarction and dyskinesia associated with cerebral infarction	2006
Alginic Sodium Diester Injection	Ischemic heart disease, cerebrovascular diseases (cerebral thrombosis, cerebral embolism and coronary heart disease) and high lipoprotein blood disease.	2006
Bumetanide for Injection	Various edema diseases (including those associated with heart failure, hepatic cirrhosis, nephropathy, and pulmonary edema), hypertension, acute renal failure, hyperkalemia, hypercalcemia and for the rescue from acute drug poisoning.	2007
Candesartan	Hypertension	2013
Anti-infection and Respiratory Diseases		
Roxithromycin Dispersible Tablets		1995

	Pharyngitis and tonsillitis caused by Streptococcus pyogenes; sinusitis, tympanitis, acute and chronic bronchitis caused by acute bacterial infection, Mycoplasma pneumonia and Chlamydia pneumoniae; urethritis and cervical infection caused by chlamydia trachomatis; skin soft tissue infection caused by sensitive bacteria.	
Cefaclor Dispersible Tablets	Tympanitis, lower respiratory tract infection, urinary tract infections and skin/skin tissue infection.	2002

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Product	Indication	Year of Commercial Launch
Cefalexin Capsules	Acute tonsillitis caused by sensitive fungi, airway infections, such as pharyngitis, otitis media, nasal sinusitis and bronchitis; pneumonia, respiratory tract infection, urinary tract infections and skin soft tissue infections.	2002
Andrographolide	Detoxification, antibacterial and anti-inflammatory. For sore throat caused by upper respiratory tract infection	2003
Clarithromycin Granules and Capsules	Nasopharynx infection, lower respiratory tract infection, skin tissue infection, acute tympanitis and mycoplasma pneumonia caused by clarithromycin susceptible organisms; urethritis and cervical infection caused by chlamydia trachomatis; and the treatment of legionella infection, mycobacterium avium complex (MAC) infection and helicobacter pylori infection.	2004
Naproxen Sodium and PseudophedrineHydrochlorida Sustained Release Tablet	Relieves cold, sinus and flu symptoms, blocked nose caused by anaphylaxis rhinitis, runny nose, fever, sore throat, symptoms of myalgia in the limbs and pain around the joints.	2005
Digestive Diseases		
Hepatocyte Growth-promoting Factor for Injection	Serious viral hepatitis symptoms caused by various viral hepatitis types (acute, subnormal temperature, chronic serious disease early or middle period of hepatitis).	2005
Tiopronin	Acute and chronic Hepatitis B, and for the relief of drug-induced liver injury.	2009
Compound Ammonium Glycyrrhetate S for Injection	Liver dysfunction caused by acute and chronic hepatitis; supplemental treatment to toxic/trauma hepatitis, liver cancer; also for the indication of food/drug poisoning, and drug allergy.	2009
Omeparzole	Gastroesophageal reflux disease, and other conditions caused by excess acidic formulations in the stomach, including gastric ulcers, recurrent duodenal ulcers and Zollinger-Ellison Syndrome.	2009
Others		
Vitamin B6 for Injection	Vitamin supplement.	2005
Granisetron Hydrochloride Injection	Nausea and vomiting caused by radiotherapy and chemotherapy during the treatment of malignant tumors.	2006

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The following table sets forth the aggregate amount our revenues attributed to our product portfolio by indication group for the years ended December 31, 2018 and 2017.

Product Category	Year Ended December 31, 2018	2017	Net Change	% Change	
CNS Cerebral & Cardio Vascular	2.41	2.07	0.34	16	%
Anti-Viral/ Infection & Respiratory	6.76	8.05	-1.29	-16	%
Digestive Diseases	0.72	0.69	0.03	5	%
Other	2.44	2.40	0.04	2	%

Due to the nature of the pharmaceutical industry, we continually strive to change our product portfolio to respond to changes in market demand. Based on a foundation established by a number of our widely-recognized prescription products, such as Cefaclor and Roxithromycin, we have launched and will continue to launch a variety of pharmaceuticals. The core criteria for our selection of potential pipeline products are strong market demand, proven efficacy, and safety. In an effort to gain an advantage in the marketplace, we often seek to improve the production process of the new generic products we elect to manufacture or to improve the quality of a proposed product to increase its efficacy.

We also adjust the delivery systems and marketing for each of our products based on the product's target patient group. We believe that maintaining a variety of delivery systems (e.g. tablet, capsules, injectables and dry powders) for certain of our products targeted at different groups enhances our competitive position in the marketplace. As a result, our sales and marketing personnel work closely with management and our research and development personnel to determine which of our products can successfully be marketed for more than one delivery system and which generic drugs in the marketplace may be good candidates for us to manufacture and distribute using different delivery systems.

Product Development

Research & development and innovation represent the core competitive advantage for a company's sustainable growth. For pharmaceutical companies, products with proprietary intellectual property are not only strategic resources for comprehensive strength, but also important tools to engage in social responsibility. We have been focusing on the research and development of both first generic drugs and innovative drugs. Additionally, we also have actively worked to meet unsatisfied medical needs by sticking to a market-oriented approach and continuously improving the effectiveness and ease of use of our drugs, supported by a well-designed system for intellectual property management.

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Our product portfolio includes both branded and generic drugs that we either develop independently, in joint research efforts with our academic institutional partners, or, to a lesser extent, acquire from third parties. We develop new products in-house as well as in cooperation with several research institutes. We only pay these institutes for their research efforts and expenses if our research goals are accomplished as evidenced by the certification of an applicable drug candidate and the approval of drug production by the CFDA. Following receipt of such certification and approval, the rights to the applicable drug candidate are transferred to us. Upon any such payment and transfer, we become the sole owner of the drug certifications and/or the approvals of drug production and any related research, and we have no further payment or other obligations to the research institute from which we acquired such assets. We also intend to continue purchasing or obtaining licenses from third parties to produce certain drug products on a limited basis, as we regard this as an important and effective means for us to develop our business. New products in our pipeline have experienced delays because the CFDA enhanced its approval criteria and processes, resulting in additional supplemental materials and trials, higher cost, and longer approval time for certain applications across all pharmaceutical products, including all of our product types.

Generic drugs are drugs with the same active ingredient, dosage form, delivery channel and therapeutic effects as the originally-developed drug. The Consistency Evaluations require currently marketed generic products to prove their consistency in terms of quality and therapeutic effect, and the ability to act as a substitute for the original drug during clinical trials. The Consistency Evaluations could enhance the development of the pharmaceutical industry, ensure drug safety and effectiveness, promote the improvement and restructuring of the pharmaceutical industry, and increase international competitiveness.

The PRC State Council issued “Opinions on Carrying out Consistency Evaluation on Quality and Efficacy of Generic Drugs” on March 5, 2016, requiring all manufacturers of generic chemical pipeline products to carry out Consistency Evaluations before they may obtain final registration approval. Drugs failing to meet these requirements may not be re-registered.

Currently, due to this newly issued policy, as with all other Chinese generic pharmaceutical companies, the CFDA production approved standards and experimental requirements for almost all of our pipeline products have undergone major adjustments. Management decided to terminate the development and research of some of the product formulations after it had fully evaluated the technical difficulties, investment expectations, and expected future market returns of product formulations under the new standard.

Due to the complex implementation rules of Consistency Evaluations that are still being introduced, we suspended the development of some of our pipeline products in 2018. The following list sets forth the current status of our main pipeline products:

Indication of Product Candidate	**CFDA Status**
Anti-infection	In Phase II clinical study, supplement clinical study due to improved technology criteria
Cholesterol Control Drug	we have submitted an application for production approval, and are supplementing Consistency Evaluation experiments per the newly issued policies
Alzheimer's Disease drug	We have completed consistency evaluation experiments. We are in the stage of pilot scale tests and trial productions.
Coronary Heart Disease Drug	Phase III clinical study completed, and are supplementing clinical trials pursuant to the updated criteria

Distribution and Customers

We believe we have a well-established sales network. As our current pharmaceutical product portfolio is comprised mainly of prescription drugs, our major sales targets are hospitals. As of December 31, 2018, we also had 16 sales offices covering all major provinces of China, and over 1,000 sales representatives who assist in managing many of our relationships with hospitals, doctors and local drug distributors. Overall, our distribution model is rather flat, with relatively few intermediaries compared to many other pharmaceutical companies in China. Due to this advantage, we believe we are able to keep our selling cost lower than the industry average.

Due to the nature of our products and current governmental regulations, all of our customers are located in the PRC. We have established long-standing relationships with most of our key customers through our operating subsidiary, Helpson, which was formed in 1993.

Production Facilities

We manufacture and package our products at our manufacturing facility in the Haikou Free Trade Zone in Haikou, Hainan Province. Our old manufacturing facility, which was built in 2002, is approximately 8,000 square meters; and our new building, approximately 20,000 square meters, was completed in 2013. We have production lines with new version of GMP certificates for different forms including: tablets, capsule, dry power, liquid injectables, solid oral solution Cephalosporins (specifically designated).

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The CFDA promulgated Good Manufacturing Practices for Pharmaceutical Products (2010 revised version) (the "New GMP Standards") on February 12, 2011, which became effective on March 1, 2011. The new GMP outlines the basic principles and standards for the manufacturing of pharmaceutical products and the management of quality controls in the manufacturing process in the PRC. Pursuant to those mandatory requirements, the upgrading of our two sterilization production lines - liquid injectables and dry powder injectables production lines were required to be completed by the end of 2013. As of January 1, 2014, we had suspended two such production lines due to the failure to meet the GMP upgrading deadline. However, construction of our new main building has been completed, and two new sterilization production lines have been installed. In November 2014 the CFDA completed their process of the GMP certification for our new facility and issued the GMP certificate to enable us to commence manufacturing our liquid injectables and dry powder injectable product lines. In January and December 2015, we also completed the upgrading and received new GMP certificates for the tablet and capsule production lines, and cephalosporin production lines in our old factories respectively.

Raw Materials

We require a supply of a wide variety of raw materials to manufacture our products. We employ purchasing staff with extensive knowledge of our products who work with our product development, and formulations and quality control personnel to source raw materials for our products. Currently, we rely on numerous suppliers in the PRC and overseas to deliver our required raw materials and believe we have at least three principal suppliers for each of our most critical raw materials. Historically, we have not had difficulty obtaining raw materials from suppliers. For the year ended December 31, 2018, our purchases from four suppliers accounted for 26.2%, 17.0% and 11.2% of raw material purchases. For the year ended December 31, 2017, our purchases from four suppliers accounted for 19.8%, 17.1%, 15.4% and 11.8% of raw material purchases.

Competition

We believe we have established a commercially competitive position in the highly-fragmented pharmaceutical industry in China through our core competitive advantages, as described below:

We have a highly-efficient commercialization process for new products, including significant experience with the CFDA registration process.

We have over 20 years of product-development experience during which time we have implemented processes to efficiently introduce and market new and existing products to the Chinese market.

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We have a market-oriented product portfolio and product lines.

Our product focus is on developing and manufacturing medicines that help large patient groups, such as the infectious disease and cardio vascular disease patient groups. Our diversified GMP-certified manufacturing facility includes various production lines targeting a variety of delivery mechanisms, such as tablets, capsules, cephalosprine tablets, cephalosprine capsules, liquid-injectables and dry powder injectables, which enables us to effectively manufacture a broad range of new drugs.

We have product diversification to target specific sub-markets.

We attempt to differentiate our products from those of our competitors by changing, and, in many cases, improving certain physical aspects of our products to market to different market segments. For example, to make our Cefaclor product more patient friendly to children and patients with swallowing problems, we added an enteric coating to make our tablets easier to swallow.

We have a national sales network and a highly-trained marketing team.

Our experienced sales team has the industry knowledge and know-how to synergistically combine our strong market insight with a successful commercialization platform.

We have developed high-quality relationships with leading hospital and clinic administrators and physicians.

While sales of our pharmaceutical products to hospitals are made through our distributors, we believe our long-term relationships with leading hospitals and healthcare clinics throughout China resulting from our long-term promotional efforts and periodic physician seminars improve the perception of our products in the marketplace and help us identify and select high-volume drugs to develop into new generic products relatively early in the process.

We cooperate effectively with a number of leading academic research institutions.

Through our cooperative efforts with leading academic research institutions, which are our research partners, we are able to develop new product candidates in a cost-effective manner and currently have a number of significant projects in active development in our pipeline.

Notwithstanding such favorable positioning, we are subject to intense competition. There are both local and overseas pharmaceutical enterprises that are engaged in the manufacture and sale of potential substitute or similar pharmaceutical products in the PRC. These competitors may have more capital, better research and development resources, better manufacturing and marketing capability, and more experience than we do.

Our profitability may be adversely affected if:

- the number of our competitors increases;
- competitors engage in increased price competition; or
- competitors develop new products or product substitutes having comparable medicinal applications or therapeutic effects that are more effective, less costly and/or have more perceived benefits than those produced by us.

In addition, imported products and China's admission as a member of the World Trade Organization ("WTO") creates increased competition. The PRC became a member of the WTO in December 2001. As a result, competition in the pharmaceutical industry in the PRC intensified generally in two respects. First, with lower import tariffs, imported pharmaceutical products manufactured overseas may become increasingly competitive in terms of pricing. Second, we believe that well-established foreign pharmaceutical manufacturers may set up production facilities in the PRC and compete with domestic manufacturers directly. With the expected increased supply of competitively-priced pharmaceutical products in the PRC, we may face increased competition from foreign pharmaceutical products, especially in terms of high-end pharmaceutical products, including certain types of products manufactured by U.S. manufacturers.

Intellectual Property

We regard our packaging designs, trademarks, trade secrets, patent and similar intellectual property as part of our core competence that is critical to our success. We rely on patent, trademark and trade secret law, as well as confidentiality agreements with certain of our employees, distributors and others to protect our intellectual property rights.

In November 2008, we purchased the patented medical formula for a cerebral/cardio-vascular indication and the manufacturing processes for that product from a third party laboratory. In connection with that acquisition, we obtained the title of the patent. This patent expires in 2025.

In 2012, we acquired another patent related to a medical formula for the treatment of cerebral/cardio-vascular diseases. This patent expires in 2029.

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As of December 31, 2018, we owned 17 registered trademarks, including marks for nine of the 19 pharmaceutical products we manufacture, including the tradenames Funalin, Fukexing, Beisha, Shiduotai, Xinuo, Pusenlitai, Pusenouke, Shuchang and Shenkaineng, as well as marks for our AFGF logo, our HPS logo, our two HELPSON logos and four other logos. The registration numbers of the 17 registered trademarks are as follows: No.1280259, No.1500459, No.1511770, No.1535416, No.1537828, No.1535420, No.1272792, No.1272759, No.1272760, No.1330294, No.1327731, No.1330295, No.1476339, No.3993785, No. 4074317, No.4074321 and No. 4315247.

Environmental Matters

We comply with the Environmental Protection Law of China as well as applicable local regulations. In addition to statutory and regulatory compliance, we actively ensure the environmental sustainability of our operations. Penalties may be levied upon us if we fail to adhere to and maintain certain standards. Such failure has not occurred in the past, and we generally do not anticipate that it will occur in the future, but no assurance can be given in this regard.

Regulations

Regulations Relating to Pharmaceutical Industry. The pharmaceutical industry in China is highly regulated. The primary regulatory authority is the CFDA, including its provincial and local branches. As a developer and producer of medicinal products, we are subject to regulation and oversight by the CFDA and its provincial and local branches. The Law of the PRC on the Administration of Pharmaceuticals provides the basic legal framework for the administration of the production and sale of pharmaceuticals in China and covers the manufacturing, distribution, packaging, pricing and advertising of pharmaceutical products. These regulations set forth detailed rules with respect to the administration of pharmaceuticals in China. We are also subject to other PRC laws and regulations that are applicable to business operators, manufacturers and distributors in general.

Registration and Approval of Medicine. Pursuant to the PRC Provisions for Drug Registration, a medicine must be registered and approved by the CFDA before it can be manufactured and sold. The registration and approval process requires the manufacturer to submit to the CFDA a registration application containing detailed information concerning the efficacy and quality of the medicine and the manufacturing process and the production facilities the manufacturer expects to use. A series of policies on consistency evaluation and drug review process have been issued in recent years, and potentially more reforms and adjustments are underway in order to promote the pharmaceutical industry in China in line with international standards. In this context, we believe that the uncertainties in the timetables for obtaining CFDA production approvals for products under research are increasing. f a manufacturer chooses to manufacture a pre-clinical medicine, it is also required to conduct pre-clinical trials, apply to the CFDA for permission to conduct clinical trials and go through the clinical trials. If a manufacturer chooses to manufacture a post-clinical medicine, it only needs to go through the clinical trials. In both cases, a manufacturer needs to file clinical data with the CFDA for approval for manufacturing after clinical trials are completed.

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New Medicine. If a new medicine is approved by the CFDA, the CFDA will issue a new medicine certificate to the manufacturer and impose a monitoring period of one to five years. During the monitoring period, the CFDA will monitor the safety of the new medicine, and will neither accept new medicine certificate applications for an identical medicine by another pharmaceutical company, nor approve the production or import of an identical medicine by other pharmaceutical companies. As a result of these regulations, the holder of a new medicine certificate has the exclusive right to manufacture it during the monitoring period. We currently have new medicine certificates for our Pusenouke, Cefaclor dispersible tablets and Roxithromycin dispersible tablets and Bumetanide for injection products.

National Production Standard and Provisional Standard. In connection with the CFDA's approval of a new medicine, the CFDA will normally direct the manufacturer to produce the medicine according to a provisional national production standard, or a provisional standard. A provisional standard is valid for two years, during which time the CFDA closely monitors the production process and quality consistency of the medicine to develop a national final production standard for the medicine, or a final standard. Three months before the expiration of the two-year period, the manufacturer is required to apply to the CFDA to convert the provisional standard to a final standard. Upon approval, the CFDA will publish the final standard for production. The CFDA has no statutory timeline to complete its review and grant approval for the conversion. In practice, the approval for conversion to a final standard is time-consuming and could take a number of years. However, during the CFDA's review period, the manufacturer may continue to produce the medicine according to the provisional standard.

Transitional Period. Prior to the latter of (1) the expiration of a new medicine's monitoring period or (2) the date when the CFDA grants a final standard for a new medicine after the expiration of the provisional standard, the CFDA will not accept applications for an identical medicine nor will it approve the production of an identical medicine by other pharmaceutical companies. Accordingly, the manufacturer will continue to have an exclusive production right for the new medicine during this transitional period.

Continuing CFDA Regulation

Pharmaceutical manufacturers in China are subject to continuing regulation by the CFDA. If the labeling or its manufacturing process of an approved medicine is significantly modified, a new pre-market approval or pre-market approval supplement will be required by the CFDA. A pharmaceutical manufacturer is subject to periodic inspection and safety monitoring by the CFDA to determine compliance with regulatory requirements.

The CFDA has a variety of enforcement actions available to enforce its regulations and rules, including fines and injunctions, recall or seizure of products, the imposition of operating restrictions, partial suspension or complete shutdown of production and criminal prosecution.

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Pharmaceutical Product Manufacturing

Permits and Licenses for Pharmaceutical Manufacturers. A pharmaceutical manufacturer must obtain a pharmaceutical manufacturing permit from the CFDA's relevant provincial branch. This permit is valid for five years and is renewable for an additional five-year period upon its expiration. Our current pharmaceutical manufacturing permit, issued by the CFDA, will expire on December 31, 2020. We are confident the permit could be renewed before its expiration.

Good Manufacturing Practice. A pharmaceutical manufacturer must meet the Good Manufacturing Practice standards, or GMP standards, for each of its production facilities in China in respect of each form of pharmaceutical product it produces. GMP standards include staff qualifications, production premises and facilities, equipment, raw materials, environmental hygiene, production management, quality control and customer complaint administration. If a manufacturer meets the GMP standards, the CFDA will issue to the manufacturer a Good Manufacturing Practice certificate, or a GMP certificate, with a five-year validity period. However, for a newly-established pharmaceutical manufacturer that meets the GMP standards, the CFDA will issue a GMP certificate with only a one-year validity period. The New GMP Standards became effective on March 1, 2011 and pharmaceutical manufacturers (except manufacturers of injectables, blood products or vaccines, which have a three-year grace period) have a five-year grace period to upgrade existing facilities to comply with the revisions.

We obtained three GMP certificates for our manufacturing facility in respect of the majority form of pharmaceutical products we produce, one is valid until October 30, 2019 (lyophilized powder for injection, small volume parenteral solutions), the second is valid until January 2020 (tablets, capsules), and the third is valid until December 6, 2020 (tables, capsule - cephalosprins). All of our GMP certificates are valid for five years. While we are required to implement certain upgrades to our manufacturing facilities to comply with the new GMP standards, we do not currently anticipate any difficulty in renewing these certificates when we finish the facility upgrading.

Product Liability and Consumers Protection

Product liability claims may arise if any pharmaceutical products have a harmful effect on a consumer, and result in an injured party making a claim for damages or compensation. The General Principles of the Civil Law of the PRC, which became effective in January 1987, state that manufacturers and sellers of defective products causing property damage or injury shall incur civil liabilities for such damage or injuries.

The Product Quality Law of the PRC was enacted in 1993 and amended in 2000 to strengthen the quality control of products and protect consumers' rights and interests. Under this law, manufacturers and distributors who produce or sell defective products may be subject to confiscation of earnings from such sales, revocation of business licenses and imposition of fines, and in severe circumstances, may be subject to criminal liability.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and became effective on January 1, 1994 to protect consumers when they purchase or use goods or services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. In extreme situations, pharmaceutical product manufacturers and distributors may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Price Controls

The State Council of China promulgated the "Notice on Printing and Advocating Opinions on Promoting the Reform of Drug Prices" in 2015. Not including narcotic drugs and psychotropic drugs of the first category, the prices of drugs originally designed by the government were abolished beginning in June 1, 2015. At the same time, it encourages to improve the drug procurement mechanism, optimize medicine-fees-control effect of medical insurance, and allow the actual transaction prices of drugs being formed per market competition.

The authority calls for strengthening the role of medical insurance in medicine-fees-control. It promotes the reform of payment systems such as the compound payment system and the medical insurance monitoring system; and urges to further improve the "bargaining negotiation mechanism" between medical insurance departments and designated medical institutions. At the same time, taking into account the affordability of medical insurance funds and insured patients, the clinical efficacy of medical insurance drugs and other factors, to formulate medical insurance drug payment standards, and effectively play the guiding role of medical insurance payment standards on market prices.

On February 12, 2018, the State Council Information Office held a press release on deepening medical reform and improving medical services. Mr. Wang Hesheng, deputy director of the National Health and Family Planning Commission and director of the State Council's Medical Reform Office, reiterated the current policy: It is strictly forbidden to link the income of medical personnel with the income of medicines, consumables, and inspections, and to control the unreasonable growth of medical expenses scientifically. The increase in the organization's medical expenses dropped from 21% in 2010 to about 10% in 2017. With respect to drug use, drug prices are reduced through various measures such as centralized bidding and procurement, national negotiations on drug prices, and control of irrational use of drugs. The latest round of price reductions for pharmaceuticals in the province as a unit averaged more than 15%.

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Other Regulations

In addition to the regulations relating to pharmaceutical industry in China, we are also subject to the regulations applicable to a foreign invested enterprise in China.

Foreign Currency Exchange. Pursuant to the Foreign Currency Administration Rules promulgated in 1996 and amended in 1997 and various regulations issued by the State Administration of Foreign Exchange, or the SAFE, and other relevant PRC government authorities, Renminbi is freely convertible only to the extent of current account items, such as trade-related receipts and payments, interests and dividends. Capital account items, such as direct equity investments, loans and repatriation of investment, require the prior approval from the SAFE or its local counterpart for conversion of Renminbi into a foreign currency, such as U.S. dollars, and remittance of the foreign currency outside the PRC.

Payments for transactions that take place within the PRC must be made in Renminbi. Unless otherwise approved, PRC companies other than foreign investment enterprises (FIEs) must convert foreign currency payments they receive from abroad into Renminbi. On the other hand, FIEs may retain foreign currency in accounts with designated foreign exchange banks, subject to a cap set by the SAFE or its local counterpart.

Dividend Distribution. Under the PRC regulations governing dividend distributions by wholly foreign-owned enterprises and Sino-foreign equity joint ventures, wholly foreign-owned enterprises and Sino-foreign equity joint ventures in the PRC may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. Additionally, these foreign-invested enterprises are required to set aside certain amounts of their accumulated profits each year, if any, to fund certain reserve funds. These reserves are not distributable as cash dividends.

Employees

As of December 31, 2018, we had 252 employees, among which 240 employees were full-time employees and 12 employees were temporary employees. None of our employees is represented by a labor union and, in general, we consider our relationship with our employees to be good.

As required by applicable Chinese law, we have entered into employment contracts with substantially all of our officers, managers and employees. We are working towards entering into employment contracts with those employees

who do not currently have employment contracts with us. The PRC enacted a new Labor Contract Law, which became effective on January 1, 2008. We have updated our employment contracts and employee handbook and are in compliance with such law.

ITEM 1A. RISK FACTORS

Risks Related to our Business and our Industry

The commercial success of our products depends upon the degree of their market acceptance among the medical community. If our products do not attain market acceptance among the medical community, our operations and profitability would be adversely affected.

The commercial success of our products depends upon the degree of market acceptance they achieve within the medical community, particularly among physicians and hospital administrators. Physicians may not prescribe or recommend our products to patients and procurement departments of hospitals may not purchase our products if physicians or hospital pharmacists do not find our products attractive. The acceptance and use of our products among the medical community will depend upon a number of factors, including:

perception of physicians, patients and others in the medical community as to the safety and effectiveness of our products;

the prevalence and severity of any side effects;

the pharmacological benefit of our products relative to competing products and products under development;

the efficacy and potential advantages of our products relative to competing products and products under development;

the relative convenience and ease of administration of our products;

the methods by which our pharmaceutical products may be delivered to patients;

the effectiveness of our education, marketing and distribution efforts and those of our distributors;

publicity concerning our products or competing products and treatments; and

the price of our products and competing products.

If we fail to meet the New GMP Standards, the production at certain of our old production lines will be suspended and our operations and profitability would be adversely affected.

We are in the process of upgrading our old production facilities to bring them in line with the New GMP Standards which became effective as of March 1, 2011. In November 2014, the CFDA completed their process of reviewing our new facility and issued GMP certificates authorizing us to commence manufacturing liquid injectable and dry powder injectable product lines. In January and December 2015, we completed upgrades and received new GMP certificates for tablet and capsule production lines and cephalosporin production lines in our old factories.

We may be subject from time to time to product recalls initiated by us or by the CFDA. Product recalls could impose significant costs on us and adversely affect our ability to generate revenue.

In our business, we must comply with a variety of product safety and product testing regulations. In particular, our products are subject to, among other statutes and regulations, those issued by the CFDA. If the CFDA issues any notices to cease the production, sale and use of any of our products, we must comply with such requirements. As a result, we may incur significant costs in complying with cessation requirements, and our financial results could be materially and adversely affected. Furthermore, concerns about potential liability or potential future changes in product safety regulations may lead us to voluntarily recall or otherwise discontinue selling selected products, which could materially and adversely affect our results of operations.

In March 2013, CFDA issued a nationwide notice (the "CFDA Notice") for the cessation of the production, sale and use of Buflomedil effective immediately. The CFDA Notice was a result of the reevaluation done by the CFDA based on the indications from the recent Chinese and international research materials, which found that the risks of side effects to the nervous system and the cardiovascular system from Buflomedil have surpassed its clinical treatment benefits. The CFDA Notice was applicable to all the manufacturers and distributors in China who are in the business of the production and sale of Buflomedil related products. As a result, we no longer produce Buflomedil after 2013.

Recalls may also harm our reputation, increase our costs and reduce our net sales. Governments and regulatory agencies in the markets where we manufacture and sell products may enact additional regulations relating to product safety and consumer protection in the future or take other actions that may adversely impact our business. The CFDA has the authority to revoke drug approvals previously granted and remove from the market previously approved products for various reasons.

If we fail to develop new products with high profit margins and our high-profit-margin products are replaced by competitors' products, then our gross and net profits margins will be adversely affected.

We had gross profit margins of 16.0% for the year ended December 31, 2018, compared to gross profit margins of 18.7% for the year ended December 31, 2017. The pharmaceutical market in the PRC remains very competitive, and there may be pressure to reduce sale prices of products without a corresponding decrease in the cost of sold products. To the extent that we fail to develop new products with high profit margins and our high-profit-margin products are replaced by our competitors' products, our gross profit margins and net profit margins will be adversely affected. In addition, in the event that our products are included in the National Essential Drug List (the "EDL"), which is subject to strict governmental price controls, our gross profit margin and net profit margins could be adversely affected notwithstanding any increase in our revenues that may result from the listing of such products on the EDL.

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Our products face substantial competition. Other companies may discover, develop, acquire or commercialize products earlier or more successfully than we do.

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases that treat similar medical conditions. Many of our products may compete against products that have lower prices, superior performance, greater ease of administration or other advantages compared to our products. We would face enhanced competition if competitive products are added to the National Medical Insurance Program. Our inability to compete effectively could reduce sales or margins, which could have a material adverse effect on our results of our operations.

Some of our competitors are actively engaged in research and development in areas in which we have products or in which we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. If alternatives to our products are dispensed or prescribed to patients, the volume of our competing products sold may decline or we may be required to lower the prices of our competing products to remain competitive, either of which could negatively impact our sales. In addition, an increasing number of foreign pharmaceutical companies have introduced their pharmaceutical products into the Chinese market. Competitive products introduced by these companies can also negatively impact our sales and results of operations.

Large Chinese state-owned and privately owned pharmaceutical companies and foreign-invested or foreign pharmaceutical companies may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do. In addition, some of our competitors may have technical or competitive advantages over us with respect to the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. There may also be significant consolidation in the pharmaceutical industry among our competitors. Alliances may develop among competitors, and these alliances may rapidly acquire significant market share.

Furthermore, in order to gain market share in China, competitors may significantly increase their advertising expenditures and promotional activities or even engage in irrational or predatory pricing behavior. In addition, our competitors may engage in inappropriate competition or illegal acts, such as bribery. Third parties may actively engage in activities designed to undermine our brand name and product quality or to influence customer confidence in our products. Increased competition may result in price reductions, reduced margins and loss of market share, any of which could materially adversely affect our profit margins. We may not be able to compete effectively against current and future competitors.

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Most of our products are off-patent branded generics that can be manufactured and sold by other pharmaceutical manufacturers in the PRC once the relevant protection or monitoring periods, if any, elapse.

Most of our products are off-patent branded generic pharmaceuticals and are not protected by intellectual property rights. As a result, other pharmaceutical companies may sell equivalent products at a lower cost, and this might result in a commensurate loss in sales of our branded generic products or require us to lower our prices to compete. Certain of our generic products are subject to protection during the CFDA's monitoring period. During such period, the CFDA will not accept applications for new medicine certificates for the same product by other pharmaceutical companies or approve the production or import of the same product by other pharmaceutical companies. Once such monitoring periods expire, other manufacturers may obtain relevant production approvals and will be entitled to sell generic pharmaceutical products with similar formulae or production methods in China. The maximum monitoring period currently granted by the CFDA is five years from the date the CFDA production approval is issued. As a result, we expect to face increased competition for our products following the expirations of their respective monitoring periods. If other pharmaceutical companies sell pharmaceutical products that are similar to our unprotected products or our protected products for which the relevant protection or monitoring period has expired, we may face additional competition and our business and profitability may be adversely affected.

Our business depends in part on our well-known Helpson brand name, and if we are not able to maintain and enhance our brand recognition to maintain our competitive advantage, our reputation, business and operating results may be harmed.

We believe that market awareness of our Helpson brand has contributed significantly to the success of our business. We also believe that maintaining and enhancing the Helpson brand is critical to maintaining our competitive advantage. Although our sales and marketing staff will continue to further promote our brand to remain competitive, we may not be successful. If we are unable to further enhance our brand recognition and increase awareness of our products, or if we are compelled to incur excessive marketing and promotion expenses in order to maintain our brand awareness, our business and results of operations may be materially and adversely affected. Furthermore, our sales and results of operations could be adversely affected if the Helpson brand or our reputation is impaired by recalls or negative publicity for one of our branded products, and certain actions taken by our distributors, competitors, third-party marketing firms or relevant regulatory authorities.

Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.

Market acceptance and sales of our products also depend to a large extent on the reimbursement policies of the PRC government. The Ministry of Labor and Social Security of the PRC or provincial or local labor and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the national

medical insurance catalog or provincial or local medical insurance catalogs for the National Medical Insurance Program every other year, and catalogs under which a drug will be classified affects the amounts reimbursable to program participants for their purchases of those medicines. These determinations are made based on a number of factors, including price and efficacy. Generally, there are two catalogs, the National Insurance Catalogue ("NIC") and the EDL on which a product can be included. The products selected for the EDL generally are selected from the NIC. A consumer can be reimbursed for the full cost of a medicine on the EDL and can be reimbursed for 80% to 90% of the cost of a medicine listed on the NIC. Our Vitamin B6, Cefalexin, Clarithromycin and Omeprazole products are currently included in the EDL. If government authorities decide to remove these products from the medicine catalogs, such removal may reduce the affordability of our products and change the public perception regarding our products, which, in turn, would adversely affect the sales of these products and reduce our net revenue. Furthermore, if we are unable to obtain approval from the relevant government authorities to include our new products in the national, provincial or local medicine catalogs, sales of our new products maybe materially and adversely affected.

The growth and success of our business depend on our ability to successfully market our principal products to hospitals and their selection in tender processes used by hospitals for medicine purchases.

Our future growth and success significantly depend on our ability to successfully market our principal products to hospitals as prescription medicines. Approximately 90% of the end-customers of our products are hospitals. Hospitals may make bulk purchases of a medicine included in the national and provincial medicine catalogs only if that medicine is selected under a government-administered tender process. A hospital's interest in a particular medicine is evidenced by:

the inclusion of this medicine on the hospital's formulary, which establishes the scope of medicines physicians at this hospital may prescribe to their patients, and

the willingness of physicians at a hospital to prescribe this medicine to their patients.

We believe effective marketing efforts are critical in ensuring that hospitals and physicians are interested in purchasing our products. If our marketing efforts are not effective, hospital administrators may not want to include our products in their formularies or may remove them from their formularies, or physicians may not be interested in prescribing our products to their patients. As a result, we may find it difficult to maintain the existing level of sales of our products, and our revenues and profitability may decline.

Our future research and development projects may not be successful.

The successful development of pharmaceutical products can be influenced by many factors. Products that appear to be promising in their early phases of research and development may fail to be commercially viable for various reasons, such as failing to obtain the necessary regulatory approvals. Additionally, the research and development process for new products for which we may obtain an approval certificate is long. The process of conducting basic research and various stages of tests and trials of a new product before obtaining an approval certificate and commercializing the product may require ten years or longer. A few of our product candidates are in the early stages of pre-clinical study and clinical trials and we must conduct a significant number of additional clinical trials before we can seek the regulatory approvals necessary to begin commercial production and sales of these products. We cannot guarantee that our future research and development projects will be successful or completed within their anticipated time frames or budgets or that we will receive the necessary approvals from the relevant authorities for the production of these newly developed products, or that these newly-developed products will achieve commercial success.

Our competitors may obtain approval for a competitive product before the product we are developing is approved. If this occurs, we may be precluded from getting approval until the competitor's monitoring period expires and realize little to no benefit from our research and development investment.

Even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expect. Additionally, the pharmaceutical industry is characterized by rapid changes in technology, constant enhancements of industry know-how and the frequent emergence of new products. Future technological improvements and continual product developments in the pharmaceutical market may render our existing products obsolete or affect their viability and competitiveness. Therefore, our future success will largely depend on our development capability, including our ability to improve our existing products, diversify our product range and develop new and competitively-priced products that can meet the requirements of the changing market. Should we fail to respond to these frequent technological advances by failing to improve our existing products, develop new products in a timely manner, or have these products reach a desirable level of market acceptance, our business and profitability will be materially and adversely affected.

We cooperate with research institutions and universities in the PRC for the research and development of certain new products and any failure of such research institutions to meet our timing and quality standards or our failure to continue such collaborative arrangement or enter into such new arrangements could adversely affect our ability to develop new pharmaceuticals and our overall business prospects.

Our business strategy includes collaborating with third parties for the research and development of new products. We have maintained long-term cooperative relationships with a number of research institutions and universities in the PRC. These research institutions and universities have collaborated with us in a number of research projects and certain of our products that have obtained approval certificates were developed by such research institutions. At present, several research institutions and universities are working with us on various research and development projects. Any failure of such research institutions to meet the required quality standards and timetables set forth in their research agreements with us, or our inability to enter into additional research agreements with these research institutions on terms acceptable to us in the future, may have an adverse effect on our ability to develop new medicines and on our business prospects. Additionally, the growth of our business and development of new products may require that we seek additional research institutions. We cannot assure you that we will be able to enter into agreements with new parties on terms acceptable to us. Our inability to enter into such agreements or our failure to maintain such arrangements could limit the number of new products that we develop and ultimately decrease our sources of future revenue.

We may not be able to obtain regulatory approval for any of the new products and failure to obtain these approvals could materially harm our business.

All new medicines must be approved by the CFDA before they can be marketed and sold in the PRC. The CFDA requires successful completion of clinical trials and demonstrated manufacturing capability before it grants approval. It often takes a number of years before a medicine can be ultimately approved by the CFDA. In addition, the CFDA and other regulatory authorities may apply new standards for safety, manufacturing, packaging, and distribution of future product candidates.

Complying with such standards may be time-consuming and expensive and could result in delays in obtaining CFDA approval for our future product candidates, or possibly preclude us from obtaining CFDA approval altogether. For example, due to the enhanced criteria introduced during the implementation process of the trial of one of our products in the dried powder injectable and granule production lines in our old plant, the clinical trials lasted longer than originally expected. Furthermore, our future products may not be effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval and prevent or limit their commercial use. The CFDA and other regulatory authorities may not approve the products that we develop and even if we do obtain regulatory approvals, such regulatory approvals may be subject to limitations on the indicated uses for which we may market a product, which may limit the size of the market for such product.

New product development in the pharmaceutical industry is time-consuming and costly and has a low rate of successful commercialization.

Our success will depend in part on our ability to enhance our existing products and to develop new products. The development process for pharmaceutical products is complex and uncertain, as well as time-consuming and costly. Relatively few research and development programs produce a commercial product. A product candidate that appears promising in the early phases of development may fail to reach the market for a number of reasons, such as:

the failure to demonstrate safety and efficacy in preclinical and clinical trials;

the failure to obtain approvals for intended use from relevant regulatory bodies, such as the CFDA;

our inability to manufacture and commercialize sufficient quantities of the product economically; and

proprietary rights, such as patent rights, held by others to our product candidates and their refusal to sell or license such rights to us on reasonable terms, or at all.

Delays in any part of the development process or our inability to obtain regulatory approval of our products could adversely affect our operating results by restricting or delaying our introduction of new products. Even if we successfully commercialize new products, these products may address markets that are currently being served by our mature products and may result in a reduction in the sales volume of our mature product or vice versa. Failure to develop, obtain necessary regulatory clearances or approvals for or successfully commercialize or market potential new products or technologies could have a material adverse effect on our financial condition and results of operations.

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We may not be able to successfully identify and acquire new products or businesses.

In addition to our own product development efforts, our growth strategy also relies on our acquisitions of new product candidates, products or businesses from third parties. Any future growth through acquisitions will be dependent upon the continued availability of suitable acquisition candidates at favorable prices and favorable terms and conditions. Even if such opportunities are present, we may not be able to successfully identify them. Moreover, other companies, many of which may have substantially greater financial, marketing and sales resources, are competing with us for the right to acquire such product candidates, products or businesses.

We depend on distributors for all of our revenues and failure to maintain relationships with our distributors or to otherwise expand our distribution network would materially and adversely affect our business.

We sell our products exclusively to pharmaceutical distributors in the PRC and depend on distributors for all of our revenues. We have business relationships with over 1,000 distributors in the PRC. For the year ended December 31, 2018, no customer accounted for more than 10.0% of sales, and two customers accounted for 49.1%, 10.6% of accounts receivable. In line with industry practices in the PRC, we enter into written sales agreements with our distributors. However, such sales agreements are not in substance equivalent to a typical distribution agreement in the United States. Each sales agreement is more in the form of a sales order and specifies one or several purchases of one or more products without any continuing obligation to purchase any additional amount of products. In the event certain distributors choose not to continue their relationship with us after completing their existing sales agreements, they can do so without breaching any contract or agreement, our financial results could be adversely affected if we cannot find the substantially similar distributors in time under such circumstances. In addition, some of our distributors may sell products that compete with our products. We compete for desired distributors with other pharmaceutical manufacturers, many of which may have higher visibility, greater name recognition, financial resources, and broader product selection than we do. Consequently, maintaining relationships with existing distributors and replacing distributors may be difficult and time-consuming. Any disruption of our distribution network, including our failure to renew our existing distribution agreements with our desired distributors, could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, financial condition and results of operations.

We rely on a limited number of distributors for the majority of sales of our products.

We rely on a limited number of distributors for most of our net revenue. Our top five distributors in the aggregate accounted for 12% and 14% of our net revenues in 2018 and 2017, respectively. We expect that a relatively small number of our distributors will continue to account for a major portion of our net revenue in the near future. Our dependence on a few distributors may expose us to the risk of substantial losses if a single large distributor stops purchasing our products, purchases lower quantities of our products or goes out of business and we cannot find

substitute distributors on equivalent terms. If any of our significant distributors reduces the quantity of the products they purchase from us or stops purchasing from us, our net revenue would be materially and adversely affected.

Our operations may be affected if we could not pass the Consistency Evaluation requirement issued by the State Council for any of our current existing products.

Generic drugs refer to drugs with the same active ingredient, dosage form, delivery channel and therapeutic effects compared to the original drugs. The "Consistency Evaluation" requires currently marketed generic products to prove their consistency in term of quality and therapeutic effect, and substitutability during clinical trials with original drug. The Consistency Evaluation could enhance the development of pharmaceutical industry, ensure drug safety and effectiveness, promote the upgrading and restructuring the pharmaceutical industry, and improve international competitiveness.

The PRC State Council issued the "Opinions on Carrying out Consistency Evaluations on Quality and Efficacy of Generic Drugs" ("Opinions") on March 5, 2016, requiring all chemical generic pipeline products to carry out Consistency Evaluations before final registration approval. In addition, all oral solution generic drugs listed in National Essential Drugs List (2012 edition) and launched into market before October 1, 2007, must complete their Consistency Evaluations by the end of 2018. Consistency Evaluations must be completed by the end of 2021 for drugs with existing special condition or those require clinical efficacy trials. Drugs fail to meet requirements shall not be re-registered. As of today, all of our products in pipe lines were postponed in receiving their CFDA approvals due to this additional new requirement and the Company is working to accelerate the process.

The "Opinions" stress that the drug manufacturers are subject to Consistency Evaluations. Therefore, if we fail to complete Consistency Evaluations for our generic drugs per the government's requirements, our business and operation will be negatively impacted.

Our operations may be affected if we could not obtain raw materials from our current key suppliers on acceptable terms.

We require a supply of a wide variety of raw materials to manufacture our products. Currently, we rely on numerous suppliers in the PRC and overseas to deliver our required raw materials and believe we have at least three principal suppliers for each of our most critical raw materials. For the year ended December 31, 2018, three suppliers accounted for 26.2%, 17.0%, 11.2% of raw material purchases and the year ended December 31, 2017, purchases from four suppliers accounted for 19.8%, 17.1%, 15.4% and 11.8% our raw material purchases.

Historically, we have not had difficulty obtaining raw materials from suppliers. However, we cannot predict the impact on our suppliers of the current economic environment and other developments in their respective businesses. Insolvency, financial difficulties or other factors may result in our suppliers not being able to fulfill the terms of their

agreements with us. Furthermore, such factors may render suppliers unwilling to extend contracts that provide favorable terms to us or may force them to seek to renegotiate existing contracts. Although we believe we have alternative sources of supply for the raw materials used in our business, termination of our relationships with any of our key suppliers could have a material adverse effect on our business, financial condition or results of operations in the unlikely event that we are unable to obtain adequate raw materials from other sources in a timely manner or at all.

We may not be able to effectively manage our employees and distribution network, and our reputation, business, prospects and brand may be materially and adversely affected by actions taken by our distributors and third party marketing firms.

We have limited ability to manage the activities of our distributors and third-party marketing firms that we contract to promote our products and brand name, which are independent from us. Our distributors and third-party marketing firms could take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and brand:

sell our products outside their designated territory, possibly in violation of the exclusive distribution rights of other distributors;

fail to adequately promote our products;

promote competing products in lieu of our products; or

violate the anti-corruption laws of China, the United States or other countries.

Additionally, although our company policies prohibit our employees from making improper payments to hospitals or otherwise engaging in improper activities to influence the procurement decisions of hospitals, we may not be able to effectively manage our employees, as the compensation of our sales and marketing personnel is partially linked to their sales performance. As a result, we cannot assure you that our employees will not violate the anticorruption laws of the PRC, the United States and other countries. Such violations could have a material adverse effect on our reputation, business, prospects and brand.

Failure to adequately manage our employees, distribution network or third-party marketing firms, or their non-compliance with employment, distribution or marketing agreements could harm our corporate image among hospitals and end users of our products and disrupt our sales, resulting in a failure to meet our sales goals. Furthermore, we could be liable for actions taken by our employees, distributors or third-party marketing firms, including any violations of applicable law in connection with the marketing or sale of our products, including China's anticorruption laws and the Foreign Corrupt Practices Act of the United States, or the FCPA. In particular, if our employees, distributors or third-party marketing firms make any payments that are forbidden under the FCPA, we could be subject to civil and criminal penalties imposed by the U.S. government.

Recently, the PRC government has increased its anti-corruption measures. In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by hospitals and medical practitioners from pharmaceutical manufacturers and distributors in connection with the prescription of certain pharmaceuticals. Our employees, affiliates, distributors or third-party marketing firms may violate these laws or otherwise engage in illegal practices with respect to their sales or marking of our products or other activities involving our products. If our employees, affiliates, distributors or third-party marketing firms violate these laws, we could be required to pay damages or fines, which could materially and adversely affect our financial condition and results of operations. In addition, PRC laws regarding the types of payments to promote or sell our products that are impermissible are not always clear. As a result, we, our employees, affiliates, our distributors or third-party marketing firms could make certain payments in connection with the promotion or sale of our products or other activities involving our products which at the time could be reasonably determined to be legal but are later deemed impermissible by the PRC government. Furthermore, our brand and reputation, our sales activities or the price of our common stock could be adversely affected if we become the target of any negative publicity as a result of actions taken by our employees, affiliates, distributors or third-party marketing firms.

We have limited insurance coverage and may incur losses resulting from product liability claims, business interruptions or claims that could be covered by D&O Insurance.

The nature of our business exposes us to the risk of product liability claims that is inherent in the research and development, manufacturing and marketing of pharmaceutical products. Using product candidates in clinical trials also exposes us to product liability claims. These risks are greater for our products that receive regulatory approval for commercial sale. Even if a product is approved for commercial use by an appropriate governmental agency, there can be no assurance that users will not claim effects other than those intended resulted from the use of our products. While no material claim for personal injury resulting from allegedly defective products has been brought against us to date, a substantial claim or a substantial number of claims, if successful, could have a material adverse impact on our business, financial condition and results of operations. Such lawsuits may divert the attention of our management from our business strategies, may be costly to defend and may negatively impact our reputation and our Helpson brand's reputation, and harm the sales of our other branded products. In addition, product liability insurance for pharmaceutical products is not available in the PRC. In the event of allegations that any of our products are harmful, we may experience reduced consumer demand for our products or our products may be recalled from the market. We may also be forced to defend lawsuits and, if unsuccessful, to pay a substantial amount in damages, legal fees, and other related expenses. In addition, business interruption insurance available in the PRC offers limited coverage compared to that offered in many other countries. We do not have any business interruption insurance. Any business disruption or natural disaster could result in substantial costs and diversion of resources. Lastly, we currently do not have directors and officers insurance. In the event we or any of our directors or officers are sued under any proceedings or actions that could be covered by a standard D&O insurance, we may incur substantial costs and expenses to defend such case.

Our future liquidity needs are uncertain and we may need to raise additional funds in the future.

Based on our current operating plans, we expect our existing resources to be sufficient to fund our existing operations for at least 12 months. However, we may be required to raise additional funds to expand our operations. In addition, we may, need to raise additional funds if our expenditures exceed our current expectations. This could occur for a number of reasons, including:

we decide to devote significant amount of financial resources to the development of products that we believe to have significant commercialization potential;

we decide to acquire or license rights to additional product candidates or new technologies;

some or all of our product candidates fail in clinical trials or pre-clinical studies or prove not to be as commercially promising as we expect and we are forced to develop or acquire additional product candidates;

our product candidates require more extensive clinical or pre-clinical testing or clinical trials of these product candidates take longer to complete than we currently expect; or

we decide or are required to conduct more high-throughput screening than expected against current or additional disease targets to develop additional product candidates.

Our ability to raise additional funds in the future is subject to a variety of uncertainties, including:

our future financial condition, results of operations and cash flows;

general market conditions for capital-raising activities by pharmaceutical companies; and

economic, political and other conditions in China and elsewhere.

We cannot assure you that our revenues will be sufficient to meet our operational needs and capital requirements. If we need to obtain external financing, we cannot assure you that financing will be available in amounts or on terms acceptable to us, if at all. Our future liquidity needs and other business reasons could require us to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or equity-linked securities could result in additional dilution to our stockholders. The incurrence of additional indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations.

We may undertake acquisitions in the future, and any difficulties in integrating these acquisitions may damage our profitability.

In the future, we may acquire additional businesses or products that complement our existing business and expand our business scale. The integration of new businesses and products may prove to be an expensive and time consuming procedure. We can offer no assurance that we will be able to successfully integrate the newly acquired businesses and products or operate the acquired business in a profitable manner. Failure to locate an appropriate acquisition target, failure to successfully integrate and operate acquired businesses and products, and failure to identify substantial

liabilities associated with acquired businesses, may materially adversely impact our operations and profits.

The failure to manage growth effectively could have an adverse effect on our business, financial condition and results of our operations.

The rapid market growth of our pharmaceutical products may require us to expand our employee base for managerial, operational, financial and other purposes. As of December 31, 2018, we had 242 employees. Our future development will impose significant responsibilities upon the members of management to identify, recruit, maintain, integrate and motivate new employees. Aside from the increased difficulties in the management of human resources, we may also encounter working capital issues, as we need increased liquidity to finance the purchases of raw materials and supplies, research and development and purchase of drug formulas for new products, acquisition of new businesses and technologies, and the hiring of additional employees. For effective growth management, we will be required to continue improving our operations, management, and financial systems and control. Our failure to manage growth effectively may lead to operational and financial inefficiencies that will have a negative effect on our profitability.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially Ms. Zhilin Li, our Chairman, President and Chief Executive Officer. The loss of Ms. Li's services would adversely affect our ability to develop and market our products. We also depend in part on the continued services of our key scientific personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We face intense competition for qualified personnel, and the existence of noncompetition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Certain of our employees and consultants were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, or at universities or other research institutions. Although no claims against us are currently pending, we may be subject to claims that these employees or consultants have, inadvertently or otherwise, used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

We are subject to environmental regulations and may be exposed to liability and potential costs for environmental compliance.

We are subject to PRC laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our manufacturing processes. We are required to establish and maintain facilities to dispose of waste and report the volume of waste to the relevant government authorities, which conduct scheduled or unscheduled inspections of our facilities and treatment of such discharge. There may be situations where we may not be in full compliance with environmental regulations. Any violation of these regulations could result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligation to take corrective measures. Our cost of complying with current and future environmental protection laws and regulations and our liabilities which may potentially arise from the discharge of effluent water and solid waste may materially adversely affect our business, financial condition and results of operations. The government may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our pollution control equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations.

Power shortages, natural disasters, terrorist acts or other calamities could disrupt our production and have a material adverse effect on our business, financial position and results of operations.

All of our products are produced at our manufacturing facility in Hainan, China. A significant disruption at that facility, even on a short-term basis, could impair our ability to timely produce and ship products, which could have a material adverse effect on our business, financial position and results of operations. Our manufacturing operations are vulnerable to interruption and damage from natural and other types of disasters, including earthquake, fire, floods, environmental accidents, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously impaired. For example, a once-in-forty-year 16 grade super typhoon Rammasun hit Haikou on July 18, 2014, which caused us approximately $2.3 million (RMB14.2 million) in losses. Part of a warehouse was flooded, some damage was caused to our new facility, and the water and electricity supply was suspended for several days, causing a brief halt to our production activities and a delay in our obtaining GMP certification.

In addition, we do not maintain any insurance other than property insurance for some of our buildings and equipment. Accordingly, unexpected business interruptions resulting from disasters could disrupt our operations and thereby result in substantial costs and diversion of resources. Our production process requires a continuous supply of electricity. We have encountered power shortages historically due to restricted power supply to industrial users during summers when the usage of electricity is high and supply is limited or as a result of damage to the electricity supply

network. Because the duration of those power shortages was brief, they had no material impact on our operations. Longer interruptions of electricity supply could result in lengthy production shutdowns, increased costs associated with restarting production and the loss of production in progress. Any major suspension or termination of electricity or other unexpected business interruptions could have a material adverse impact on our business, financial condition and results of operations.

The discontinuation of any preferential tax treatments or other incentives currently available to us in the PRC could materially and adversely affect our business, financial condition and results of operations.

Prior to January 1, 2008, pursuant to the original Income Tax Law of the PRC for Enterprises with Foreign Investment and Foreign Enterprises and its implementation rules, a foreign invested enterprise as defined under PRC laws was required to pay a 30% corporate income tax and a 3% local income tax; an enterprise with foreign investment of a production nature scheduled to operate for a period of not less than ten years was, from the year of making profits, exempt from enterprise income tax in the first and second years and allowed a fifty percent reduction in the third to fifth years. Pursuant to the State Council's Regulations on Encouraging Investment in and Development of Hainan Island promulgated in May 1988, the corporate income tax for all companies incorporated in Hainan Province was reduced to 15%. Pursuant to the Regulations on Foreign Investment in Hainan Special Economic Zone promulgated by Hainan Province in March 1991 (the "Regulation on Foreign Investment"), all foreign-invested enterprises incorporated in Hainan Province are exempt from the local income tax.

However, on March 16, 2007, China's national congress approved the Enterprise Income Tax Law of the PRC ("New Income Tax Law"), which took effect on January 1, 2008. The New Income Tax Law unified the enterprise income tax rate, cost deductions and tax incentive policies for both domestic and foreign-invested enterprises. Under the New Income Tax Law, enterprises that were established and already enjoyed preferential tax rates or tax holidays before March 16, 2007 will (i) in the case of preferential tax rates, gradually increase to a 25% rate over a period of five years, (ii) in the case of tax holidays, continue to receive the benefit of such holidays until the expiration of such term.

As a result, we enjoyed a preferential tax rate of 9%, 10% and 11% in the years of 2008, 2009 and 2010. We obtained the High Tech Enterprise status from the PRC government in 2010 and we enjoyed a 15% income tax rate for a three-year period from 2011 to 2013. We applied for continued High Tech Enterprise status in 2013, with its associated favorable tax rate, and we received an extension of the 15% income tax rate for a second three-year period from 2014 to 2016. However, our recent net loss results have put the Company in an unfavorable position for the potential renewal of "National High-Tech Enterprise" status in 2017, and after evaluating the feasibility of such a renewal, the Company has decided not to renew this status. As a result, our tax rate for 2018 and the foreseeable future will be 25%. The discontinuation of any of our existing special or preferential tax treatment as mentioned above or other incentives could have an adverse effect on our business, financial condition and results of operations.

The recently enacted U.S. tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, U.S. President Donald Trump signed into law the "Tax Cuts and Jobs Act," which significantly amended the Internal Revenue Code. The Tax Cuts and Jobs Act, among other things, reduces the U.S. corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted earnings, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced

rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits. We continue to examine the impact these changes may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Cuts and Jobs Act on holders of our shares is also uncertain and could be adverse. We urge our shareholders to consult with their legal and tax advisers with respect to the Tax Cuts and Jobs Act and the potential tax consequences of investing in our shares.

We cannot guarantee the protection of our intellectual property rights, and if infringement or counterfeiting of our intellectual property rights occurs, then our reputation and business may be adversely affected.

To protect the brand names of our products, we have registered and applied for registration of certain of our trademarks in the PRC. Currently eight of the 20 pharmaceutical products we manufacture are marketed under a brand registered as a trademark in China. We also purchased a pharmaceutical compound from a third party that we are seeking to develop into a further product. To date, we have not experienced any infringements of our trademarks for sales of pharmaceutical products or our exclusive patent license, and we are not aware of any infringement of our intellectual property rights. However, there is no guarantee that there will not be any infringements of our brand name or other registered trademarks or counterfeiting of our products in the future. There is no guarantee that there will not be any third-party infringement of our patents. Should any such infringement or counterfeiting occur, our reputation and business may be adversely affected. We may also incur significant expenses and substantial amounts of time and effort to protect our intellectual property rights in the future. Such diversion of our resources may adversely affect our existing business and future expansion plans.

Litigation may be necessary in the future to enforce our intellectual property rights or to determine the validity and scope of the intellectual property rights of others. However, because the validity, enforceability and scope of protection of intellectual property rights in the PRC are uncertain and still evolving, we may not be successful in prosecuting these cases. In addition, any litigation or proceeding or other efforts to protect our intellectual property rights could result in substantial costs and diversion of our resources and could seriously harm our business and operating results. Furthermore, the degree of future protection of our proprietary rights is uncertain and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we are unable to protect our trade names, trade secrets and other propriety information from infringement, our business, financial condition and results of operations may be materially and adversely affected.

Risks Related to Doing Business in China

Adverse changes in political and economic policies of the PRC government could have a material and adverse effect on the overall economic growth of China, which could reduce the demand for our services and materially and adversely affect our competitive position.

We conduct substantially all of our business and have historically derived all of our revenues in China. Accordingly, our business, financial condition, results of operations and prospects are affected significantly by economic, political and legal developments in China. The Chinese economy differs from the economies of most developed countries in many respects, including:

the degree of government involvement;

the level of development;

the growth rate;

the control of foreign exchange;

access to financing; and

the allocation of resources.

While the Chinese economy has experienced significant growth in the past 30 years, growth has been uneven, both geographically and among various sectors of the economy. The Chinese economy has also experienced certain adverse effects due to the recent global financial crisis. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our operating results and financial condition may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us, and by government policies or guidance aimed at curtailing the perceived over-capacity of certain industry sectors, such as pharmaceutical companies. The Chinese government has implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which could in turn reduce the demand for our products and materially and adversely affect our operating results and financial condition.

The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of the productive assets in China is still owned by the Chinese government. The continued control of these assets and other aspects of the national economy by the Chinese government could materially and adversely affect our business.

The Chinese government also exercises significant control over Chinese economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

Any adverse change in the economic conditions or government policies in China could have a material and adverse effect on overall economic growth and the level of investments in health industries in China, which in turn could lead to a reduction in demand for our products and consequently have a material and adverse effect on our business.

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The PRC legal system has inherent uncertainties that could limit the legal protections available to us.

The PRC legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In the late 1970s, the PRC government began to promulgate a comprehensive system of laws and regulations governing commercial matters. The overall effect of legislation enacted over the past 20 years has significantly enhanced the protections afforded to foreign-invested enterprises in China. However, these laws, regulations and legal requirements are relatively recent and are evolving rapidly, and their interpretation and enforcement involve uncertainties. These uncertainties could limit the legal protections available to foreign investors.

The practical effect of the PRC legal system on our business operations in China can be viewed as two separate but intertwined considerations. First, as a matter of substantive law, the Foreign Invested Enterprise laws provide significant protection from government interference. In addition, these laws guarantee the full benefit of corporate articles and contracts to Foreign Invested Enterprise participants. These laws, however, do impose standards concerning corporate formation and governance that are not qualitatively different from the corporation laws found in the United States. Similarly, PRC accounting laws mandate accounting practices that may not be consistent with the U.S. generally accepted accounting principles. PRC accounting laws require that an annual “statutory audit” be performed in accordance with PRC accounting standards and that the account books of a foreign invested enterprise be maintained in accordance with PRC accounting laws. Article 14 of the PRC Wholly Foreign-Owned Enterprise Law requires a wholly foreign-owned enterprise to submit certain periodic fiscal reports and statements to designated financial and tax authorities. If a foreign-invested enterprise refuses to keep account books in China, the financial and tax authorities may impose a fine on it, and the industry and commerce administration authority may order it to suspend operations or may revoke its business license.

Second, while the enforcement of substantive rights may be less clear than United States procedures, foreign-invested enterprises and foreign wholly-owned enterprises are PRC registered companies that enjoy the same status as other PRC registered companies in business-to-business dispute resolutions. The PRC legal infrastructure, however, is significantly different in operation from its United States counterpart, and may present a significant impediment to the operation of a foreign invested enterprise.

PRC economic reform policies or nationalization could result in a total investment loss in our common stock.

Since 1979, the PRC government has been in the process of reforming its economic policies. Because many reforms are unprecedented or experimental, they are expected to be refined and improved over time. Other political, economic and social factors, such as political changes, changes in the economic growth rates, unemployment or inflation, or in the disparities in per capita wealth between regions within China, could lead to further readjustment of the reform measures. This refinement and readjustment process may negatively affect our operations.

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Although the PRC government owns the majority of productive assets in China, in the past several years the government has implemented economic reform measures that emphasize decentralization and encourage private economic activity. Because these economic reform measures may be inconsistent or ineffectual, there are no guarantees that:

We will be able to capitalize on economic reforms;

The PRC government will continue its pursuit of economic reform policies;

The economic policies, even if pursued, will be successful;

Economic policies will not be significantly altered from time to time; or

Business operations in China will not become subject to the risk of nationalization.

Over the last few years, China's economy has registered high growth rates. Recently, there have been indications that rates of inflation have increased. In response, the Chinese government recently has taken measures to curb this excessively expansive economy. These measures have included restrictions on the availability of domestic credit, reducing the purchasing capability of some of its customers, and limited recentralization of the approval process for purchases of certain foreign products. These austere measures alone may not succeed in slowing down the economy's excessive expansion or control inflation, and may result in severe dislocations in the Chinese economy. The PRC government may adopt additional measures to further combat inflation, including the establishment of freezes or restraints on certain projects or markets. These measures may adversely affect our operations.

There is no guarantee that the reforms to China's economic system will continue or that we will not be adversely affected by changes in China's political, economic, and social conditions and by changes in policies of the PRC government, such as changes in laws and regulations, measures which may be introduced to control inflation, changes in the rate or method of taxation, imposition of additional restrictions on currency conversion and remittance abroad, and reduction in tariff protection and other import restrictions.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in the PRC against our company or our management based on U.S. or other foreign laws.

Our operating subsidiary, Helpson, is incorporated under the laws of the PRC and substantially all of our assets are located in the PRC. Additionally, substantially all of our directors, executive officers and managers reside within the

PRC, and substantially all of the assets of these persons are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon certain of our directors, executive officers or managers, including with respect to matters arising under U.S. federal securities laws or applicable state securities laws. Moreover, the PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. As a result, recognition and enforcement in the PRC of judgments of a court in the United States and any of the other jurisdictions mentioned above in relation to any matter may be difficult or impossible. Furthermore, an original action may be brought in the PRC against us, our directors, executive officers or managers only if the actions are not required to be arbitrated by PRC law and Helpson's articles of association, and only if the facts alleged in the complaint give rise to a cause of action under PRC law. In connection with any such original action, a PRC court may impose civil liability, including monetary damages.

Because we receive substantially all of our revenue in Renminbi, which currently is not a freely convertible currency, and the PRC government controls the currency conversion and the fluctuation of the Renminbi, we are subject to changes in the PRC's political and economic decisions.

We receive substantially all of our revenues in Renminbi, which currently is not a freely-convertible currency. The PRC government may, at its discretion, restrict access in the future to foreign currencies for current account transactions. Any future restrictions on currency exchanges may limit our ability to use revenue generated in Renminbi to fund any future business activities outside China or to make dividend or other payments in U.S. dollars. Although the Chinese government introduced regulations in 1996 to allow greater convertibility of the Renminbi for current account transactions, significant restrictions still remain, including primarily the restriction that foreign-invested enterprises may only buy, sell or remit foreign currencies, after providing valid commercial documents, at those banks authorized to conduct foreign exchange business. In addition, conversion of Renminbi for capital account items, including direct investment and loans, is subject to governmental approval in China, and companies are required to open and maintain separate foreign exchange accounts for capital account items.

We cannot be certain that the Chinese regulatory authorities will not impose more stringent restrictions on the convertibility of the Renminbi, especially with respect to foreign exchange transactions.

Fluctuation in the value of the Renminbi may have a material and adverse effect on your investment. The change in value of the Renminbi against the U.S. dollar is affected by, among other things, changes in PRC's political and economic conditions. From 1995 until July 2005, the People's Bank of China intervened in the foreign exchange market to maintain an exchange rate of approximately Renminbi 8.3 per U.S. dollar. On July 21, 2005, the PRC government changed this policy and began allowing modest appreciation of the Renminbi versus the U.S. dollar. Under the new policy, the Renminbi was permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy caused the Renminbi to appreciate approximately 21.5% against the U.S. dollar over the following three years. As a consequence, the Renminbi has fluctuated sharply since July 2008 against other freely traded currencies, in tandem with the U.S. dollar. It is difficult to predict how long the current situation may last and when and how it may change again. There remains significant international pressure on the PRC government to adopt a substantial liberalization of its currency policy, which could result in a further and more significant appreciation in the value of the Renminbi against the U.S. dollar. Significant revaluation of the Renminbi may have a material adverse effect on your investment. For example, to the extent that we need to convert U.S. dollars we receive from securities offering into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive from the conversion. Conversely, if we decide to convert our Renminbi into U.S. dollars for the purpose of making payments for dividends on our common stock or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount available to us. In August 2015, the PRC Government devalued its currency by approximately 3%, represented the largest yuan depreciation for 20 years. Concerns remain that China's slowing economy, and in particular its exports, will need a stimulus that can only come from further cuts in the exchange rate.

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In addition, appreciation or depreciation in the value of the Renminbi relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. The income statements of our operations are translated into U.S. dollars at the average exchange rates in each applicable period. To the extent the U.S. dollar strengthens against foreign currencies, the translation of these foreign currencies denominated transactions results in reduced revenue, operating expenses and net income for our international operations. Similarly, to the extent the U.S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions results in increased revenue, operating expenses and net income for our international operations. We are also exposed to foreign exchange rate fluctuations as we convert the financial statements of our foreign subsidiaries into U.S. dollars in consolidation. If there is a change in foreign currency exchange rates, the conversion of the foreign subsidiaries' financial statements into U.S. dollars will lead to a translation gain or loss, which is recorded as a component of other comprehensive income. Very limited hedging transactions are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions. While we may enter into hedging transactions in the future, the availability and effectiveness of these transactions may be limited, and we may not be able to successfully hedge our exposure at all.

We are subject to the environmental protection laws of the PRC that may be costly to comply with and may adversely affect our manufacturing operations.

Our manufacturing process may produce by-products, such as effluent, gases and noise, which are harmful to the environment. We are subject to multiple laws governing environmental protection, such as "The Law on Environmental Protection in the PRC" and "The Law on Prevention of Effluent Pollution in the PRC," as well as standards set by the relevant governmental bodies determining the classification of different wastes and proper disposal. We have properly attained a waste disposal permit for our manufacturing facility, which details the types and concentration of effluents and gases allowed for disposal. We are responsible for periodically renewing this waste disposal permit. There is no assurance that we will obtain a renewal of the waste disposal permit when the current permit expires.

China is experiencing substantial problems with environmental pollution. Accordingly, it is likely that the national, provincial and local governmental agencies will adopt stricter pollution controls. There is no guarantee that future changes in environmental laws and regulations will not impose costly compliance requirements on us or otherwise subject us to future liabilities. Our business's profitability may be adversely affected if additional or modified environmental control regulations are imposed upon us.

Failure to comply with PRC regulations regarding the registration requirements for employee equity incentive plans may subject our PRC citizen employees or us to fines and other legal or administrative sanctions.

On March 28, 2007, the SAFE promulgated the Application Procedure of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Holding Plan or Share Option Plan of Overseas-Listed Company, which were superseded by Notice from SAFE regarding Issues related to Domestic Individual Participating Offshore Public Company Equity Incentive Plan promulgated on February 15, 2012 ("SAFE #7") or the Share Option Rule. Under the Share Option Rule, PRC citizens who are granted stock options or other employee equity incentive awards by an overseas publicly-listed company are required, through a PRC agent who may be a PRC subsidiary of such overseas publicly-listed company, to register with the SAFE and complete certain other procedures related to the share options or other employee equity incentive plans. We and our PRC citizen employees who are granted share options or other equity incentive awards under our 2010 Long-Term Incentive Plan, or PRC optionees, are subject to the Share Option Rule. If we or our PRC optionees fail to comply with these regulations, we or our PRC optionees may be subject to fines and legal sanctions.

The enforcement of new labor contract law and its implementation rules and increase in labor costs in the PRC may adversely affect our business and our profitability.

China adopted the PRC Employment Contract Law, or the new Labor Contract Law, effective January 1, 2008 and the implementation rules effective September 18, 2008. The new Labor Contract Law and its implementation rules impose more stringent obligations on employers for, among others, entering into written employment contracts, hiring temporary employees, dismissing employees, setting compensations for dismissal and protecting certain sick or disabled employees from dismissal and setting forth detailed requirements relating to the contents of the employment contracts. The implementation of the new Labor Contract Law may increase our operating expenses, in particular our personnel expenses, as the continued success of our business depends significantly on our ability to attract and retain qualified personnel. In the event that we decide to terminate some of our employees or otherwise change our employment or labor practices, the new Labor Contract Law may also limit our ability to effect those changes in a manner that we believe to be cost-effective or desirable, which could adversely affect our business and results of operations.

PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the proceeds we receive from securities offerings to make loans or additional capital contributions to our PRC operating subsidiary.

In utilizing the proceeds we receive from a securities offering, as an offshore holding company with a PRC subsidiary, we may make loans to our PRC subsidiary, or we may make additional capital contributions to our PRC subsidiary. Any loans to our PRC subsidiary are subject to PRC regulations and approvals. For example, loans to our PRC

subsidiary Helpson, which is a foreign-invested enterprise, to finance its activities cannot exceed statutory limits and must be registered with the State Administration of Foreign Exchange in China, or SAFE, or its local counterpart. Loans by us to domestic PRC enterprises must be approved by the relevant government authorities and must also be registered with the SAFE or its local counterpart. Any capital contributions to our PRC subsidiary must be approved by the Ministry of Commerce in China or its local counterpart. On August 29, 2008, SAFE promulgated Circular 142, a notice regulating the conversion by a foreign-invested company of foreign currency into Renminbi by restricting how the converted Renminbi may be used. The notice 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 specifically provided for otherwise.

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 Foreign Exchange Administration Rules. We cannot assure you that we will be able to obtain these government registrations or approvals on a timely basis, if at all, with respect to our future loans or capital contributions to our direct or indirect subsidiaries. If we fail to receive such registrations or approvals, our ability to use the proceeds from a securities offering and to capitalize our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and ability to fund and expand our business.

The 2006 M&A Rule establishes more complex procedures for some acquisitions of Chinese companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

On August 8, 2006, six PRC regulatory agencies, namely, the Ministry of Commerce, the State Assets Supervision and Administration Commission, or SASAC, the State Administration for Taxation, the State Administration for Industry and Commerce, the CSRC and SAFE, jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the 2006 M&A Rule, which became effective on September 8, 2006. The 2006 M&A Rule establishes additional procedures and requirements that could make some acquisitions of PRC companies by foreign entities, such as our company, more time-consuming and complex, including requirements in some instances that the approval of the Ministry of Commerce shall be required for transactions involving the shares of an offshore listed company being used as the acquisition consideration by foreign entities, including Sino-foreign joint ventures. In the future, we may grow our business in part by acquiring complementary businesses. Complying with the requirements of the 2006 M&A Rule to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the Ministry of Commerce, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

Our China-sourced income is subject to PRC withholding tax under the new Enterprise Income Tax Law of the PRC, and we may be subject to PRC enterprise income tax at the rate of 25% when more detailed rules or precedents are promulgated.

We are a Nevada holding company with substantially all of our operations conducted through our operating subsidiary in China. Under the new PRC Enterprise Income Tax Law, or the new EIT Law, and its implementation rules, both of which became effective on January 1, 2008, China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its overseas parent, is generally subject to a 10% withholding tax. The new EIT Law, however, also provides that enterprises established outside China whose "de facto management bodies" are located in China are considered "tax resident enterprises" and will generally be subject to the uniform 25% enterprise income tax rate as to their global income. Under the implementation rules, "de facto management bodies" are defined as the bodies that have, in substance, overall management control over such aspects as the production and business, personnel, accounts and properties of an enterprise. In April 2009, the PRC tax authority promulgated the Notice on Determination of Tax Resident Enterprises of Chinese-controlled Offshore Incorporated Enterprises in accordance with Their De Facto Management Bodies, or Circular 82, to clarify the criteria for determining whether the "de facto management bodies" are located within the PRC for enterprises incorporated overseas with controlling shareholders being PRC enterprises. As all of the our operational management is currently based in the PRC, and we expect them to continue to be located in China, 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, which excludes the dividends received directly from another PRC resident enterprise. Due to the lack of clear guidance on the criteria pursuant to which the PRC tax authorities will determine our tax residency under the new EIT Law, it remains unclear whether the PRC tax authorities will treat us as a PRC resident enterprise. Therefore, we are unable to confirm whether we are subject to the tax applicable to resident enterprises or non-resident enterprises under the new EIT Law. Furthermore, in connection with the new EIT Law and Tax Implementation Regulations, the Ministry of Finance and State Administration of Taxation jointly issued, on April 30, 2009, the Notice on Issues Concerning Process of Enterprise Income Tax in Enterprise Restructuring Business, or Circular 59, which became effective retrospectively on January 1, 2008. It is uncertain to us as to how it will be implemented and the respective tax base and the tax exposure cannot be determined reliably at this stage. In case we are required to pay the income tax on capital gains by the relevant PRC tax authorities, our financial conditions and results of operations could be adversely affected.

Dividends payable by us to our foreign investors and gain on the sale of our shares may become subject to taxes under PRC tax laws.

Under the new EIT law and its implementation rules, to the extent that we are considered a "resident enterprise" which is "domiciled" in China, PRC income tax at the rate of 10% is applicable to dividends payable by us to investors that are "non-resident enterprises" so long as such "non-resident enterprise" investors do not have an establishment or place of business in China or, despite the existence of such establishment or place of business in China, the relevant income is not effectively connected with such establishment or place of business in China. Similarly, any gain realized on the transfer of our shares by such investors is also subject to a 10% PRC income tax if such gain is regarded as income derived from sources within China and we are considered a "resident enterprise" which is domiciled in China for tax purposes. Additionally, there is a possibility that the relevant PRC tax authorities may take the view that our purpose

is that of a holding company, and the capital gain derived by our overseas stockholders would be deemed China-sourced income, in which case such capital gain may be subject to PRC withholding tax at the rate of up to 10%. If we are required under the new EIT law to withhold PRC income tax on our dividends payable to our foreign stockholders who are “non-resident enterprises”, or if you are required to pay PRC income tax on the transfer of our shares under the circumstances mentioned above, the value of your investment in our shares may be materially and adversely affected. It is unclear whether, if we are considered a PRC “resident enterprise,” holders of our shares would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas.

The strengthened scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on our acquisition strategy.

In connection with the new EIT Law, the Ministry of Finance and State Administration of Taxation jointly issued, on April 30, 2009, the Notice on Issues Concerning Process of Enterprise Income Tax in Enterprise Restructuring Business, or Circular 59. On December 10, 2009, the State Administration of Taxation issued the Notice on Strengthening the Management on Enterprise Income Tax for Non-resident Enterprises Equity Transfer, or Circular 698. Both Circular 59 and Circular 698 became effective retrospectively on January 1, 2008. By promulgating and implementing these circulars, the PRC tax authorities have strengthened their scrutiny over the direct or indirect transfer of equity interest in a PRC resident enterprise by a non-resident enterprise. For example, Circular 698 specifies that the PRC State Administration of Taxation is entitled to redefine the nature of an equity transfer where offshore vehicles are interposed by abusing corporate structures for tax-avoidance purposes and without reasonable commercial intention. We may pursue acquisitions as one of our growth strategies, and may conduct acquisitions involving complex corporate structures. We cannot be assured that the PRC tax authorities will not, at their discretion, adjust the capital gains thus causing us to incur additional acquisition costs.

Risks Related to our Common Stock

The market price for our common stock may be volatile which could result in a complete loss of your investment.

The market price for our common stock is likely to be highly volatile and subject to wide fluctuations in response to factors including the following:

actual or anticipated fluctuations in our quarterly operating results;

announcements of new products by us or our competitors;

changes in financial estimates by securities analysts;

conditions in the pharmaceutical market;

changes in the economic performance or market valuations of other companies involved in pharmaceutical production;

announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

economic, regulatory and political developments;

addition or departure of key personnel, or

potential litigation.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We may issue additional shares of our capital stock to raise additional cash for working capital; if we issue additional shares of our capital stock, our stockholders will experience dilution in their respective percentage ownership in the company.

We may issue additional shares of our capital stock to raise additional cash for working capital. There is no anti-dilution protection or preemptive rights in connection with our common stock. Thus, the percentage ownership of existing holders of common stock may be diluted in their respective percentage ownership in us if we issue additional shares of our capital stock.

A large portion of our common stock is controlled by a small number of stockholders and as a result, these stockholders are able to influence and ultimately control the outcome of stockholder votes on various matters.

A large portion of our common stock is held by a small number of stockholders. For instance, Heung Mei Tsui, a member of our Board of Directors, holds 21.4% and Zhilin Li, our Chief Executive Officer, holds 23.1% of our common stock, respectively, as of the date hereof. As a result, these two stockholders are able to significantly influence the outcome of stockholder votes on various matters, including the election of directors and other corporate transactions including business combinations. In addition, the occurrence of sales of a large number of shares of our common stock, or the perception that these sales could occur, may affect our stock price and could impair our ability to obtain capital through an offering of equity securities. Furthermore, the current ratios of ownership of our common stock reduce the public float and liquidity of our common stock which can in turn affect the market price of our common stock.

We are likely to remain subject to "penny stock" regulations and as a consequence there are additional sales practice requirements and additional warnings issued by the SEC.

If at any time we have net tangible assets of $5,000,000 or less and the trading price of our common stock is below $5.00 per share, the open-market trading of our common stock will be subject to the "penny stock" rules of the SEC. The "penny stock" rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability of broker-dealers to sell the common stock and may affect a

stockholder's ability to resell the common stock.

There can be no assurance that our common stock will qualify for exemption from the "penny stock" rules. In any event, even if our common stock is exempt from such rules, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the SEC the authority to restrict any person from participating in a distribution of a "penny stock" if the SEC finds that such a restriction would be in the public interest.

Stockholders should be aware that, according to SEC Release No. 34-29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differential and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market.

We are responsible for the indemnification of our officers and directors under certain circumstances which could result in substantial expenditures, which we may be unable to recoup.

Our bylaws provide for the indemnification of our directors, officers, employees, and agents, under certain circumstances, against attorney's fees and other expenses incurred by them in any litigation to which they become a party arising from their association with or activities on behalf of us. This indemnification policy could result in substantial expenditures, which we may be unable to recoup.

We have identified material weaknesses in our internal control over financial reporting, which could affect our ability to ensure timely and reliable financial reports, affect the ability of our auditors to attest to the effectiveness of our internal controls should we become an accelerated filer in the future, and weaken investor confidence in our financial reporting.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies in their annual reports to include a report of management on the reporting company's disclosure controls and procedures and internal controls over financial reporting. We became subject to this requirement commencing with our fiscal year ended December 31, 2007 and a report of our management is included under Item 9A. "Controls and Procedures" of this Annual Report on Form 10-K. As set forth in such report, our management has concluded that our internal controls over financial reporting were not effective as of December 31, 2018, and there existed a material weakness in our internal control over financial reporting as of December 31, 2018.

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We believe we are taking appropriate actions to remediate such material weakness; however, such measures may not be sufficient to address the material weaknesses identified or ensure that our controls and procedures are effective. We may also discover other material weaknesses in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in the implementation of such controls, could cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements and affect the ability of our auditors to attest to the effectiveness of our internal control over financing reporting to the extent we become an accelerated filer in the future. In addition, substantial costs and resources may be required to rectify any internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, and our business and financial condition could be adversely affected.

We do not anticipate paying cash dividends on our common stock.

You should not rely on an investment in our common stock to provide dividend income, as we have not paid any cash dividends on our common stock and do not plan to pay any in the foreseeable future. Accordingly, investors must rely on sales of our common stock after price appreciation, which may never occur, as the only way to realize any return on their investment.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies.

Historically, the SEC has taken the position that Rule 144 under the Securities Act, as amended, is not available for the resale of securities initially issued by companies that are, or previously were, blank check companies like us, to their promoters or affiliates despite technical compliance with the requirements of Rule 144. The SEC has codified and expanded this position in its amendments effective on February 15, 2008 and applies it to securities acquired both before and after that date by prohibiting the use of Rule 144 for resale of securities issued by shell companies (other than business transaction related shell companies) or issuers that have been at any time previously a shell company. The SEC has provided an important exception to this prohibition, however, if the following conditions are met: the issuer of the securities that was formerly a shell company has ceased to be a shell company; the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act; the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company. As such, due to the fact that we had been a shell company prior to October 2005, holders of “restricted securities” within the meaning of Rule 144, when reselling their shares pursuant to Rule 144, shall be subject to the conditions set forth herein.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Smaller reporting companies are not required to provide the information required by this item.

ITEM 2. PROPERTIES.

There is no private land ownership in the PRC. All land is either owned by the government of the PRC on behalf of all Chinese citizens or collectively owned by farmers. However, land use rights may be allocated by the PRC State Land Administration Bureau or its authorized branches. Helpson was granted land use rights by the PRC government for approximately 22,936 square meters of land located on Plot C09-2 in the Haikou Bonded Zone, Hainan Province, PRC in 2003. These land use rights will expire on September 10, 2063.

Helpson owns two production facilities in Haikou, Hainan Province, PRC, one of which has a construction area of 663.94 square meters and is located on the 6th floor of Standard Plant Building B, Jinpan Industrial Development Zone. The other factory, located on Plot C09-2 in the Haikou Bonded Zone, has two buildings with production area of 20,282.42 square meters, certificate number HK477872, and 6,593.20 square meters, certificate number HK122889.

In addition, Helpson rents offices located on the second floor of the Jiahai Building owned by Hainan Zhongfu Foreign Export Personnel Service Center (the “Center”) as its principal executive offices. Monthly rent at this facility is RMB 5,580 (approximately $843). The original term of the lease was 3 years, from December 1, 2010 to November 30, 2013. On December 31, 2011, this lease was superseded by a new lease, for a term of nine years, for office spaces on the second floor and the entire third floor at a monthly rent of RMB 20,000 (approximately $2,941), with a 5% increase every two years from the fourth year until the end of the term. The aggregate area of the office space rented by Helpson is 1,686 square meters (16,812 square feet).

We believe that all our properties have been adequately maintained, are generally in good condition, and are suitable and adequate for our business. However, we are anticipate a possible need for expansion and additional space as our production increases.

Mortgaged Property

Helpson entered into an eight-year construction loan facility dated June 21, 2013. The total loan facility amount is RMB80,000,000 (approximately $12.3 million), which had been fully utilized through May 7, 2014. We have

incrementally repaid the principle of RMB36 million (approximately $5.2 million) of the construction loan per the payback schedule as of January 10, 2019. The proceeds of the loan were used for and are collateralized by the construction of the Company’s new production facility and the included production line equipment and machinery. Upon the Company’s receipt of the ownership certificate over the new factory, the mortgage was formally placed on the new facility in the second quarter of 2016.

The loans referred to above are set forth in the table below:

Total Amount of the Line of Credit	Lending Institution	**Contract Period**	Interest Rate	**Properties under Mortgage**
RMB 80 million (Approximately $12.3 million)	Bank of China	July 11, 2013 to July 10, 2021	The interest rate is 5.39%, based upon 110% of the PRC government's eight-year term rate effective on the actual draw-down date, subject to annual adjustments based on 110% of the floating rate for the same type of loan on the anniversary from the draw-down date and its subsequent anniversary dates. On July 10, 2018, the interest rate was adjusted to 5.39%.	Helpson's new factory: 20,282.42 square meters (Certificate #: HK477872) and the production line equipment and machinery in the new factory

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. However, we are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our shares began trading on the NYSE American (Formerly known as NYSE MKT) on September 30, 2009 under the symbol "CPHI". Prior to September 30, 2009, our shares traded on the OTC Bulletin Board under the symbol "CPHI.OB."

Holders

As of March 26, 2019, there were approximately 147 shareholders of record of our common stock and an indeterminate number of beneficial holders who held our common stock in street name.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc., with offices at 3200 Cherry Creek South Drive, Suite 430, Denver, Colorado 80209. Their telephone number is (303) 282-4800 and fax number is (303) 282-5800.

Dividend Policy

We have never paid or declared any dividend on our common stock and we do not anticipate paying cash dividends in the foreseeable future. As a result of our holding company structure, we would rely entirely on dividend payments from our subsidiaries, Onny Investment Ltd. and Hainan Helpson Medial & Biotechnology Co., Ltd., for our cash flow to pay dividends on our common stock. The PRC government imposes controls on the conversion of Renminbi into foreign currencies and the remittance of currencies out of the PRC, which may also affect our ability to pay cash dividends in the future.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
	(a)	(b)	(c)
Equity compensation plans not approved by security holders	-	-	-
Equity compensation plans approved by security holders	-	-	3,825,000
Totals	-	-	3,825,000

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ITEM 6. SELECTED FINANCIAL DATA

As a “smaller reporting company” as defined in Item 10 of Regulation S-K, we are not required to provide the information required by this item.

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The statements contained in this report with respect to our financial condition, results of operations and business that are not historical facts are forward-looking statements. Forward-looking statements can be identified by the use of forward-looking terminology, such as “anticipate”, “believe”, “expect”, “plan”, “intend”, “seek”, “estimate”, “project”, “could” the negative thereof or other variations thereon, or by discussions of strategy that involve risks and uncertainties. Management wishes to caution the readers that any such forward-looking statements contained in this report reflect our current beliefs with respect to future events and involve known and unknown risks, uncertainties and other factors, including, but not limited to, economic, competitive, regulatory, technological, key employees, and general business factors affecting our operations, markets, growth, services, products, licenses and other factors, some of which are described in this report including in “Risk Factors” in Item 1A and some of which are discussed in our other filings with the Securities and Exchange Commission. These forward-looking statements are only estimates or predictions. No assurances can be given regarding the achievement of future results, as actual results may differ materially as a result of risks facing our company, and actual events may differ from the assumptions underlying the statements that have been made regarding anticipated events.

These risk factors should be considered in connection with any subsequent written or oral forward-looking statements that we or persons acting on our behalf may issue. All written and oral forward-looking statements made in connection with this report that are attributable to our company or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Given these uncertainties, we caution investors not to unduly rely on our forward-looking statements. We do not undertake any obligation to review or confirm analysts’ expectations or estimates or to release publicly any revisions to any forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

Business Overview & Recent Developments

We continue to feel sustained pressure from the heightened requirements of drug registration standards, consistency evaluations, and the rising costs of clinical trials in 2018. At the same time, the improvement of environmental protection tax law, air, water and soil pollution control standards and the strengthening of supervision bring about the increase of environmental protection costs. In this context, the shortage of Active Pharmaceutical Ingredients (APIs)

and intermediates leads to the increase of raw materials costs.

On March 5, 2016, the Chinese State Council issued "*Opinions on Carrying out Consistency Evaluations of the Quality and Efficacy of Generic Drugs*" (the "Opinions"). The Opinions define the objectives of evaluations, establish deadlines, determine selection criteria for reference drugs, call for a rational selection of evaluation methods, identify pharmaceutical manufacturers as the principle generic drug consistency evaluation, and set forth corresponding incentives. Subsequently, the CFDA issued "*Comments from the General Office of the State Council on the Consistency Evaluations of the Efficacy and Quality of Generic Drugs*" in May 2016, in order to further elaborate on assessment processes and related technical rules. Consistency evaluations apply to the majority of our current existing marketed and pipeline products. In this environment, the management team has assessed each pipeline product based on the adjusted CFDA approval criteria and clinical trial requirements, the estimated additional investment needed for consistency evaluation, and potential return of investment once launched into the market; and decided to terminate the progress of certain pipeline products. Complying with consistency evaluations will become our core task in the near future and will therefore significantly impact our operations as well as our industrial structure.

Under the requirements of the consistency evaluation policy, the company actively evaluated the technical difficulty, investment demand, time requirement, and investment return rate of all applicable marketed products and pipeline products. We also actively promoted the compliance process for several key products in 2018.

In order to support our existing products package we remain focused on pipeline development. We have experienced delays in obtaining approval for certain products in our pipeline because of revisions of and enhancements to CFDA approval criteria and processes. These revisions have resulted in additional supplemental materials and trials, higher costs, and longer approval times for certain applications.

The detailed implementation rules of consistency evaluations are still being introduced, and our decision making with respect to further development of our pipeline products has been adversely impacted by those uncertainties. In light of this uncertainty, we have experienced slow progress in the development of our pipeline products in 2018. The following list sets forth the current status of our main pipeline products:

Antibiotic Combination - We are currently in Phase II of clinical trials, due to increased regulatory requests for clinical review.

Rosuvastatin - Rosuvastatin is a generic form of Crestor, a drug for the treatment of high blood cholesterol levels. Clinical trials for this generic drug were completed in the fourth quarter of 2010. We have submitted an application for production approval and are supplementing consistency evaluation experiments pursuant to the Opinions.

Heart disease drug - We developed an oral solution for the treatment of coronary heart disease in our new product pipeline. This product comes with a patented Traditional Chinese Medicine (“TCM”) formula. We have completed Phase III clinical trials and are supplementing clinical trials pursuant to the updated criteria.

Alzheimer’s disease drug - We developed a drug for the treatment of Alzheimer’s disease and have completed consistency evaluation experiments. We are in the stage of pilot scale tests and trial productions.

Market Trends

Consumer demand for medicine is relatively rigid and stable and is generally unaffected by seasonal business cycles. However, we have noticed that the growth rate of the pharmaceutical manufacturing industry has been higher than GDP growth rates in China. According to the study *"Deepening The Reform of China's Medical and Healthcare System and Building A Value-Based Quality Service Delivery System*" published by the World Bank, if China maintains its existing healthcare system, total health expenditures will increase from 5.5% of GDP in 2014 to over 9% of GDP in 2035, with an average annual growth rate of 8.4%.

The rapid development of the pharmaceutical industry in China has been driven by the continuous growth of total healthcare costs, the establishment and improvement of the universal health-care insurance system, increases in medical expenditures per capita, the aging population, and changes in the disease spectrum. However, development has been negatively impacted by factors like health-care insurance cost controls and price pressure in drug tenders in recent years.

The Central Committee Political Bureau of the Communist Party of China approved the "Healthy China 2030 Plan" in August 2016, which proposed reducing personal hygiene spending to approximately 28% of total healthcare expenditures by 2020, and 25% of total healthcare expenditures by 2030.

In order to achieve the objectives of the above-mentioned Healthy China 2030 Plan in the context of an aging population and an improving universal health-care insurance system, we believe that the hygiene spending proportion of total fiscal expenditures will increase and that net annual health-care insurance expenditures will increase as well. We anticipate that the use of generic drugs as a cost-effective medical solution will be further promoted as a way to reduce the payment pressures of health-care insurance. As a generic drug company we are presented with a huge domestic market, and through further upgrades, in conjunction with consistency evaluations, could allow us to meet European and American production standards, enabling us to export our products to overseas markets.

In August 2015, the State Council promulgated "*Opinions on Reforming Examination of the Approval System for the Reform of Drugs and Medical Devices*", which was the prelude to reforms of the drug examination and approval systems, reforms of the drug registration system, consistency evaluations of generic drugs, and enhanced drug listing licensing systems, among other reforms in China. The CFDA has also subsequently introduced a number of specific measures and technical details related to various areas of the above-mentioned reforms. These policies may change the existing competitive landscape, development methods, operating patterns and rules of the pharmaceutical industry, and may have a significant impact on the strategic choices and future development models of Chinese pharmaceutical companies.

In addition, the Office of the State Council issued "*Pilot Plan for Marketing Authorization Holders*" on May 24, 2016, allowing eligible drug research and development institutions and scientific researchers to become Marketing Authorization Holders ("MAH") by obtaining drug marketing authorization and drug approval numbers from the State Council. This policy uses a management model of separating drug marketing authorization and drug production licenses, thereby allowing an MAH to produce pharmaceuticals itself or to consign production to other pharmaceutical manufacturers. This policy not only transitions our production practices to meet European and United States standards by separating drug approval and production qualifications, and therefore changing the existing model of bundling drug approval numbers to pharmaceutical manufacturers in China, but also serves as a supplement to the ongoing consistency evaluations policy. Given that a certain failure rate must be demonstrated by MAH applicants for their consistency evaluations, an applicant that passes the evaluations could consign production to an applicant who failed to optimize capacity, save on fixed costs, and reduce capital expenditures.

In general, demand for pharmaceutical products is still experiencing steady growth in China. The ongoing generic drug consistency evaluations and reform of China's drug production registration and review policies will have major effects on the future development of our industry and may change its business patterns. We will continue to actively adapt to state policy guidance and further evaluate market conditions for our current existing products, pipeline products, and competition in the market in order to optimize our development strategy.

Results of Operations for the Fiscal Year Ended December 31, 2018

Revenue

Revenue decreased by 6.7% to $12.3 million for the year ended December 31, 2018, as compared to $13.2 million for the year ended December 31, 2017. This decrease was mainly due to the negative impact around health insurance cost controls as well as policies for reducing the proportion of drug cost to total health-care spending, in conjunction with the company's efforts in controlling bad debts by more rigorous screening customs and more stringent policies on payment terms.

Set forth below are our revenues by product category in millions (USD) for the years ended December 31, 2018 and 2017:

	Year Ended December 31,				
Product Category	2018	2017	Net Change	% Change	
CNS Cerebral & Cardio Vascular	2.41	2.07	0.34	16	%
Anti-Viro/ Infection & Respiratory	6.76	8.05	-1.29	-16	%
Digestive Diseases	0.72	0.69	0.03	4	%
Other	2.44	2.40	0.04	2	%

The most significant revenue decrease in terms of dollar amount was in our Anti-Viral/Infection & Respiratory" product category, which generated $6.76 million in sales revenue in 2018 compared to $8.05 million in 2017, a decrease of $1.29 million. This decrease was mainly due to a decrease in sales of our Cefaclor Dispersible Tablets, which was a result of stricter drug pricing control policy as Group Purchasing Organization (GPO), as well as market fluctuation.

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Sales in the “CNS Cerebral & Cardio Vascular” category increased by $0.34 million to $2.41 million in 2018 compared to $2.07 million in 2017, which was mainly due to an increase in sales of Ozagrel, primarily the result of volatility in market demand. Our “Digestive Diseases” category generated $0.72 million of sales in 2018, compared to $0.69 million in 2017. Our “Other” product category generated $2.44 million of sales in 2018, compared to $2.40 million in 2017.

	Year Ended December 31,	
Product Category	2018	2017
CNS Cerebral & Cardio Vascular	19 %	16 %
Anti-Viral/ Infection & Respiratory	55 %	61 %
Digestive Diseases	6 %	5 %
Other	20 %	18 %

For the year ended December 31, 2018, revenue breakdown by product category experienced certain variances compared with that of the prior year. Sales in the “Anti-Viral/Infection & Respiratory” product category represented 55% and 61% of total sales in the years ended December 31, 2018 and 2017, respectively. The “CNS Cerebral & Cardio Vascular” category represented 19% of total revenue in 2018, compared to 16% in 2017. The “Digestive Diseases” category represented 6% and 5% of total revenue in 2018 and 2017, respectively. The “Other” category represented 20% and 18% of revenues in 2018 and 2017, respectively.

Cost of Revenue

For the year ended December 31, 2018, our cost of revenue was $10.4 million, or 84.0% of total revenue, which represented a decrease of $0.4 million from $10.7 million, or 81.3% of total revenue, in 2017.

Gross Profit and Gross Margin

Gross profit for the year ended December 31, 2018 was $2.0 million, compared to $2.5 million in 2017. Our gross profit margin in 2018 was 16.0% compared to 18.7% in 2017. This decline in our gross profit margin was mainly due to a decrease in our sales, and our fixed manufacturing overhead.

Selling Expenses

Our selling expenses for the year ended December 31, 2018 were $3.2 million, a decrease of $0.2 million compared to $3.5 million for the year ended December 31, 2017. Selling expenses accounted for 26.1% of the total revenue in 2018 compared to 26.2% in 2017.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2018 were $1.9 million, which was close to $2.0 million in 2017. General and administrative expenses accounted for 15.8% and 15.3% of our total revenues in 2018 and 2017, respectively.

Research and Development Expenses

Our research and development expenses for the year ended December 31, 2018 was $0.17 million, compared to $0.09 million in 2017. Research and development expenses accounted for 1.4% and 0.7% of our total revenues in 2018 and 2017, respectively. The consistency evaluations discussed under the "Business Overview & Recent Developments" section hereof is expected to have a significant impact on all generic products not only in our pipeline, but also throughout the existing Chinese market. Because of the continuous introduction of detailed implementation rules under this policy, our pipeline experienced slowed progress in 2018.

Bad Debt Expenses

Our bad debt expenses for the year ended December 31, 2018 was $0.6 million, which represented a decrease of $0.8 million compared to $1.4 million in 2017. The decrease in our bad debt expenses was mainly due to the change in the composition of aging of accounts receivables for the years ended December 31, 2018 compared to December 31, 2017, which came in line with the company's more stringent scrutiny upon customers' payment history.

We update our customer credit or payment terms to 180 days in order to better reflect our actual operating performance. Due to the peculiar environment affecting the Chinese pharmaceutical market, deferred payments to pharmaceutical companies by state-owned hospitals and local medicine distributors are a normal phenomenon. Our customers are primarily pharmaceutical distributors that sell our products to mostly government-backed hospitals. Therefore, the aging of our receivables from our customers tends to be longer-term.

The amount of net accounts receivable that were past due (or the amount of accounts receivable that were more than 180 days old) was $0.22 million and $1.28 million as of December 31, 2018 and 2017, respectively.

The following table illustrates our accounts receivable aging distribution in terms of percentage of total accounts receivable as of December 31, 2018 and 2017:

	December 31, 2018		December 31, 2017	
1 - 180 Days	3.8	%	5.5	%
180 - 360 Days	1.2	%	2.4	%

360 - 720 Days	0.3	%	13.6	%
> 720 Days	94.7	%	78.5	%
Total	100.0	%	100.0	%

Our bad debt allowance estimate has been updated to 0% of accounts receivable that are within 180 days old, 10% of accounts receivable that are between 180 days and 365 days old, 70% of accounts receivable that are between 365 days and 720 days old, and 100% of accounts receivable that are greater than 720 days old. In the fourth quarter of 2018 in order to better reflect our actual business performance in the fourth quarter of 2018; compared with 10% of accounts receivable that are less than 365 days old, 70% of accounts receivable that are between 365 days and 720 days old, and 100% of accounts receivable that are greater than 720 days old.

We recognize bad debt expenses per actual write-offs as well as changes of allowance for doubtful accounts. To the extent that our current allowance for doubtful accounts is higher than that of the previous period, we recognize a bad debt expense for the difference during the current period, and when the current allowance is lower than that of the previous period, we recognize a bad debt credit for the difference. The allowance for doubtful accounts was $17.8 million and $18.2 million as of December 31, 2018 and December 31, 2017, respectively. The changes in the allowances for doubtful accounts during the years ended December 31, 2018 and 2017 were as follows:

	For the Fiscal Years Ended December 31,	
	2018	2017
Balance, Beginning of Period	$18,209,734	$15,664,496
Bad debt expense	604,388	1,393,576
Foreign currency translation adjustment	(999,047)	1,151,662
Balance, End of Period	$17,815,075	$18,209,734

Impairment of Intangible Assets

Impairment of intangible assets for the year ended December 31, 2018 was $6.5 million, compared to $14.2 million in 2017. As a pharmaceutical company, we have been focusing on the development and maintenance of our intangible assets, mainly in the form of medical formulas. Because of recently implemented government policies such as consistency evaluations, our management made certain assessments regarding the impairment of our intangible assets as of December 31, 2018 and December 31, 2017 respectively, and identified two and six formulas that would likely be unable to generate positive cash flow in the foreseeable future and therefore recognized impairment loss on them accordingly.

Loss from Operations

Our operating loss for the year ended December 31, 2018 was $10.4 million, compared to an operating loss of $18.7 million in 2017.

Net Interest Expense

Net interest expense for the year ended December 31, 2018 was $0.4 million, compared to $0.5 million in 2017. The decrease is primarily due to overall decreased debt levels due to the decrease in the interest incurred in conjunction

with the construction loan facility as discussed in Note 8 to the consolidated financial statements.

Income Tax expense

Our income tax rate for our PRC subsidiary, Helpson was 25% for the year ended December 31, 2018 and 2017, respectively. Our income tax (benefit) expense was ($0.1) million and $0.1 million for the years ended December 31, 2018 and 2017, respectively. We renewed our "National High-Tech Enterprise" status with the Chinese government in the third quarter of 2013. With this designation, for the years ending December 31, 2014, 2015 and 2016, we enjoyed a preferential tax rate of 15%, which is notably lower than the statutory income tax rate of 25%. However, our recent net loss results have put the Company in an unfavorable position for the potential renewal of "National High-Tech Enterprise" status in 2017, and after evaluating the feasibility of such a renewal, the Company has decided not to renew this status. As a result, our tax rate 2018 and for Helpson for 2017 and the foreseeable future will be 25%.

Net Loss

Net Loss for year ended December 31, 2018 was $10.8 million, compared to net loss of $19.3 million for the year ended December 31, 2017. The decrease in net loss was mainly a result of the decrease in impairment of long term assets.

For the year ended December 31, 2018, loss per basic and diluted common share was $0.25, compared to loss per basic and diluted share of $0.44 for the year ended December 31, 2017.

The number of basic and diluted weighted-average outstanding shares used to calculate loss per share was 43,579,557 for both 2018 and 2017.

Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. During 2018, our Chief Executive and Chairperson advanced an aggregate of $287,423 for use in operations. Our cash and cash equivalents were $1.2 million, representing 2.6% of our total assets as of December 31, 2018, as compared to $2.0 million, representing 3.4% of our total assets as of December 31, 2017. All of the $1.2 million of cash and cash equivalents as of December 31, 2018, is considered to be reinvested indefinitely in our Chinese subsidiary, Helpson, and is not expected to be available for payment of dividends or for other payments to our parent company or to its shareholders. We entered into an eight-year construction loan facility on September 21, 2013. The total loan facility amount is RMB 80 million (approximately $11.7 million), which had been fully utilized through May 7, 2014. As of January 10, 2019, we have

accumulatively repaid the principal of RMB 36 million (approximately $5.2 million) of the construction loans, per the payback schedule. The current balance of the construction loan facility is $2.2 million as of December 31, 2018. Cash flow generated from operating activities was used to fund our daily operating expenses as well as the repayment of our loan facility.

Based on our current operating plan, management believes that cash provided by operations will be sufficient to meet our working capital needs and our anticipated capital expenditures, including expenditures for new formula acquisitions for the next twelve months. However, if circumstances change and we do not follow our operating plan as expected, we may be required to seek additional capital and/or to reduce certain discretionary spending, which could have a material adverse effect on our ability to achieve our business objectives. Notwithstanding the foregoing, we may seek additional financing as necessary for expansion purposes and when we believe market conditions are most advantageous, which may include debt and/or equity financing. Although our Chairperson and Chief Executive Officer had advanced funds of $278,696 for working capital during 2018, there can be no assurances that this will be the case in the future. An aggregate of $87,254 was repaid to the Chairperson in January, 2019. There can be no assurance that any additional financing will be available on acceptable terms, if at all.

Operating Activities

Net cash provided by operating activities was $1.3 million in the year ended December 31, 2018, compared to $0.8 million for 2017.

As of December 31, 2018, our accounts receivable was $0.9 million, a decrease of $1.4 million from $2.3 million as of December 31, 2017. The decrease was mainly due to the decrease in revenue and improvement in collection of accounts receivable in 2018.

As of December 31, 2018, total inventory was $5.1 million, a decrease of $1.3 million from $6.4 million as of December 31, 2017. This decrease was mainly due to our improved management of inventory turn-over in 2018.

Investing Activities

During the year ended December 31, 2018, net cash used in investing activities was $0.05 million, compared to $0.14 million for the year ended December 31, 2017.

Financing Activities

Cash flow used in financing activities was $2.0 million in the year ended December 31, 2018; compared to $1.5 million in the year ended December 31, 2017. In 2018, the decrease in cash flow used in financing activities was mainly due to the repayment of the RMB 15,000,000 (approximately $2.3 million) line of loan facility in 2018.

According to relevant PRC laws, companies registered in the PRC, including our PRC subsidiary, Helpson, are required to allocate at least ten percent (10%) of their after-tax net income, as determined under accounting standards and regulations in the PRC, to statutory surplus reserve accounts until the reserve account balances reach fifty percent (50%) of the companies' registered capital prior to their remittance of funds out of the PRC. Allocations to these reserves and funds can only be used for specific purposes and are not transferrable to the parent company in the form of loans, advances or cash dividends. For the years ending December 31, 2018 and 2017, Helpson's net assets totaled $27,485,000 and $40,034,000, respectively. Due to the restriction on dividend distribution to overseas shareholders, the amount of Helpson's net assets that was designated for general and statutory capital reserves, and thus could not be

transferred to our parent company as cash dividends, was $8,145,000 and $8,145,000 (50% of registered capital) for the fiscal years ended December 31, 2018 and 2017, respectively. Since the amount that Helpson must set aside for the statutory surplus fund only accounts for 29.6% and 20.3%, respectively, of its total net assets, this reserve does not have a major impact on our liquidity. There were no allocations to the statutory surplus reserve accounts during the year ended December 31, 2018.

The Chinese government also imposes controls on the conversion of RMB into foreign currencies and the remittance of currencies out of China. Our businesses and assets are primarily denominated in RMB. All foreign exchange transactions take place either through the People's Bank of China or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the People's Bank of China. Approval of foreign currency payments by the People's Bank of China or other regulatory institutions requires the submission of a payment application form together with certain invoices and executed contracts. The currency exchange control procedures imposed by Chinese government authorities may restrict Helpson, our Chinese subsidiary, from transferring its net assets to our parent company through loans, advances or cash dividends.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements.

Commitments

As of December 31, 2018, we were obligated to pay laboratories and other service providers approximately $0.30 million over approximately the next four years upon completion of various phases of contracts required to obtain CFDA production approval for our medical formulas.

Critical Accounting Policies

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. Our financial statements reflect the selection and application of accounting policies which require management to make significant estimates and judgments. The discussion of our critical accounting policies contained in Note 1 to our consolidated financial statements, "Organization and Significant Accounting Policies", is incorporated herein by reference.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Smaller reporting companies are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated balance sheets, as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018 and 2017, together with the related notes and the report of our independent registered public accounting firms, are set forth on the "F" pages of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) that are designed to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including to our Chief Executive Officer and interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15 under the Exchange Act, our management, including our Chief Executive Officer and interim Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018. Based on that evaluation, our Chief Executive Officer and interim Chief Financial Officer concluded that as of December 31, 2018, our disclosure controls and procedures were not effective to satisfy the objectives for which they are intended due to the material weakness in our internal control over financial

reporting discussed below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles and includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of a company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles and that receipts and expenditures of a company are being made only in accordance with authorizations of management and directors of a company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of a company's assets that could have a material effect on the financial statements.

Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected in a timely manner. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance with respect to financial statement preparation. In addition, the design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Therefore, any current evaluation of controls cannot and should not be projected to future periods.

Management assessed our internal control over financial reporting as of the year ended December 31, 2018. In making this assessment, management used the criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in the report entitled "Internal Control-Integrated Framework." The 2013 COSO framework summarizes each of the components of a company's internal control system, including (i) the control environment, (ii) risk assessment, (iii) control activities, (iv) information and communication, and (v) monitoring.

Based on management's assessment using the COSO criteria, management has concluded that our internal control over financial reporting was not effective as of December 31, 2018, to allow our management, employees and consultants, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely and reasonable basis and to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Our Chief Executive Officer and interim Chief Financial Officer has determined there existed a material weakness in our internal control over financial reporting as of December 31, 2018, with respect to our lack of accounting financial reporting personnel knowledgeable in US GAAP. As of the date of this report, we are undertaking steps to correct the aforementioned material weaknesses by obtaining education and training for our personnel regarding the proper accounting under U.S. GAAP and reviewing the processes to correct the identified weaknesses. Notwithstanding these material weaknesses, management has concluded that our consolidated financial statements included in this annual report are fairly stated in all material respects in accordance with U.S. GAAP for each period presented herein.

Because we are a smaller reporting company, this Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

General

Listed below are the names and ages of all our directors and executive officers at March 26, 2019, along with their positions, offices and term:

Name	Age	Position
Zhilin Li	66	Chairman, President, Chief Executive Officer and interim Chief Financial Officer
Heung Mei Tsui	62	Director
Gene Michael Bennett	71	Independent Director
Yingwen Zhang	74	Independent Director
Baowen Dong	78	Independent Director

All of our independent directors hold offices until our next annual meeting of the stockholders, at which a successor will be duly elected and qualified or until his or her earlier resignation, removal from office, death or incapacity. Non-independent directors will hold office for a term of three (3) years or when their respective successors shall have been elected and shall qualify, or upon their prior death, resignation or removal. Directors may be re-elected for successive terms. Officers serve at the discretion of the board of directors.

The following sets forth biographical information regarding the above directors and executive officers.

Zhilin Li is the Chairman, President, Chief Executive Officer and interim Chief Financial Officer of our company. She has served as a director since 2006 and as the President and Chief Executive Officer since 2005. She was a founder of Helpson, and served as Chairman and Chief Executive Officer of Helpson from 1993 to 2005. Ms. Li was formerly the president of Haikou Bio-Engineering Institute as well as the vice president of Sichuan Institute of Biology. She graduated from Sichuan University with a degree in biology.

Heung Mei Tsui has served as a director since April 28, 2009. Previously, Ms. Tsui served as a member of our board from October 2005 to February 2008. Ms. Tsui has been a self-employed businesswoman engaged in strategic investments and was previously engaged in the pharmaceutical chemical raw material import/export business. Ms.

Tsui graduated from Hunan Financial & Economic College in 1982.

Gene Michael Bennett has served as our independent director since February 2008. Presently, Mr. Bennett is advisor and management consultant to several companies in China, including Beijing Huo Chai Mutual Entertainment Technology Co. Ltd. located in Beijing, China and Epay, Ltd. located in Shenzhen, China. In addition, Mr. Bennett is the Chairman of the Board of TALENI Healthcare, Ltd. located in Orange County, California, USA. From 2013 through 2015 Mr. Bennett served as part-time CFO for Kang Jia Fu, Royal Traditional Health Investment Management Co. Ltd , located in Wuxi, Jiangsu Province, China and advisor to Swiss Capital Asia, located in Hong Kong. From 2009 through 2013, Mr. Bennett served as the CEO of American General Business Association, located in Beijing, China. Mr. Bennett was a partner of Nexis Investment Consulting Corporation based in Beijing from 2004-2009. He was a partner of ProCFO Company based in California which provided contract chief financial officer service for firms during 2000-2004. During 1998-2000, he was a basic law, accounting and tax professor at University of Hawaii, and an accounting, tax and audit professor at Chaminade University of Honolulu, Hawaii, USA. In addition, he previously served as the chief financial officer and member of the board of directors of Argonaut Computers in Southern California. Mr. Bennett worked as an accounting and audit professor at Chapman University and an accounting, tax, and audit professor at California State University at Fullerton. He also acted as chief financial officer and a board member of the National Automobile Club. Mr. Bennett graduated from Michigan State University with an MBA in Finance and BA in Accounting. He obtained his CPA license from the State of Colorado, which is currently inactive.

Yingwen Zhang has served as our independent director since February 2008. He also currently serves as a consultant of Shanghai Reseat Medical Tech Co. Ltd., a medical device producer. He acted as Senior Consultant and Chairman of HSE (Health Safe and Environment) Committee of SINOFERT Holdings Limited (HKG: 0297) of SINOCHEM Group from October 2005 to June 2009. Additionally, Mr. Zhang was appointed as the Commercial Counselor of the China Embassy in Malaysia from March 2000 through October 2005. Prior to that, from 1988 to 2000, Mr. Zhang was appointed as the Director-General to Sichuan Provincial Foreign Trade and Economic Cooperation Bureau (the Commercial Bureau of Sichuan Province, China). In his early career he was a chemical engineer and senior economist, and then became a senior manager for several chemical corporations in China. From 1983 to 1988, Mr. Zhang served as vice CEO and then CEO of a large nature gas-chemical state owned enterprise (SOE) in the PRC affiliated with the SINOPEC Group. Mr. Zhang graduated from the Chemical Engineering Department of Tianjin University in 1967.

Baowen Dong has served as our independent director since February 2008. Mr. Dong participated on the expert team of the Sichuan University from 2003 to 2008, doing teaching evaluation and assessment work in Engineering and Medical Science faculty. In the past few years, Mr. Dong has focused on the research of China's Health Care Reform. Previously, he concentrated on biomedical and medical information researches. Mr. Dong has had different roles in areas of teaching and research, including a dean and a professor, at Sichuan University from 1974 to 2001. Additionally, Mr. Dong was engaged in the field of communication technology from 1966 to 1974. Mr. Dong graduated from Xi'an University of Science and Technology in 1966.

Family Relationships

There are no family relationships among our directors or executive officers.

Director or Officer Involvement in Certain Legal Proceedings

To our knowledge, our directors and executive officers were not involved in any legal proceedings as described in Item 401(f) of Regulation S-K in the past ten years.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors, executive officers and persons who own more than 10% a registered class of our equity securities ("Reporting Persons"), to file reports of

ownership and changes in ownership on Forms 3, 4 and 5 with the SEC. The Reporting Persons are also required by SEC rules to furnish us with copies of Section 16(a) forms they file. Based upon a review of the filings made on their behalf during the fiscal year ended December 31, 2018, as well as an examination of the SEC's EDGAR system Form 3, 4, and 5 filings (including amendments to such forms) and our records, we believe that, during the year ended December 31, 2018, the Reporting Persons met all applicable Section 16(a) filing requirements.

Code of Ethics

On July 8, 2008, we adopted a code of business conduct and ethics for all directors and employees (including officers) within the meaning of the regulations adopted by the SEC under Section 406 of the Sarbanes-Oxley Act of 2002. The code has been designed to deter wrongdoing and promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships, (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications made by us, (iii) compliance with applicable governmental laws, rules and regulations, (iv) the prompt internal reporting of violations of the code to an appropriate person or persons, and (v) accountability for adherence to the code. The application of the code to the persons it applies to may only be waived by our Board of Directors in accordance with SEC regulations and the Sarbanes-Oxley Act of 2002. A copy of the code is available on our website at www.chinapharmaholdings.com or may be obtained by sending a written request to our corporate secretary at China Pharma Holdings, Inc., Second Floor, No. 17, Jinpan Road, Haikou, Hainan Province, China 570216.

Audit Committee

On February 1, 2008, we established an audit committee, which currently consists of our three independent directors: Gene Michael Bennett, Yingwen Zhang and Baowen Dong. Mr. Bennett, the Chairman of the Audit Committee, is an "audit committee financial expert" as defined in Item 401(d)(5) of Regulation S-K promulgated under the Securities Act. The audit committee carries out its responsibilities in accordance with the terms of its Audit Committee Charter, a copy of which attached as Exhibit 99.1 to our Current Report on Form 10-K filed on March 17, 2009, and available on our website at www.chinapharmaholdings.com.

ITEM 11. EXECUTIVE COMPENSATION

Summary of Executive Compensation

The following table sets forth information concerning all cash and non-cash compensation awarded to, earned by or paid to our principal executive officer and principal financial officer during the last two fiscal years in all capacities to our Company and our subsidiaries. No other executive officer received compensation in excess of $100,000 during the fiscal year ended December 31, 2018.

SUMMARY COMPENSATION TABLE

Name and principal position	Year Ended	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Zhilin Li Chairman, Chief Executive Officer	2018	225,600						16,000	241,600
President and interim Chief Financial Officer	2017	225,600	-	-	-	-	-	16,000	241,600

Employment Agreements

Zhilin Li. Hainan Helpson Medical & Biotechnology Co., Ltd., our wholly-owned subsidiary and operating entity in the PRC ("Helpson"), entered into an employment agreement with Ms. Zhilin Li, our Chairman of the Board and Chief Executive Officer, which will expire on June 30, 2015. Upon the expiration of the original agreement, Helpson renewed the agreement with Ms. Li on the same terms as the original agreement with the new expiration date of June 30, 2020. Pursuant to the terms of the new employment agreement, Ms. Li agreed to continue to serve as Helpson's Chief Executive Officer for a term of five years at an annual salary of RMB800,000. Helpson may adjust Ms. Li's compensation based upon her production and operating achievement and her technical ability and working performance. Ms. Li's total annual cash compensation for the fiscal year ended December 31, 2018, when aggregated with her compensation from our U.S. holding company level, was $225,600.

Payments upon Termination or Change-in-Control

*PRC Law.*Under the applicable laws of the PRC, we must pay severance to all employees who are Chinese nationals and who are terminated with or without cause, or whose employment agreement with us expires and we choose not to continue their employment. The severance benefit required to be paid under the laws of the PRC equals the average monthly compensation paid to the terminated employee (including any bonuses or other payments made in the 12 months prior to the employee's termination) multiplied by the number of years the employee has been employed with us, plus an additional month's salary if 30 days' prior notice of such termination has not been given. However, if the average monthly compensation to be received by the terminated employee exceeds three times the average monthly salary of the employee's local area, as determined and published by the local government, such average monthly compensation shall be capped at three times the average monthly salary of the employee's local area. Except as described above, our executive officer does not have any other agreement or arrangement under which she may be entitled to severance payments upon termination of employment.

Outstanding Equity Awards at Fiscal Year-End

None.

Discussion of Summary Compensation and Grants of Plan-based Awards Tables

A summary of certain material terms of our existing compensation plans and arrangements is set forth below.

On November 12, 2010, our Board of Directors adopted, and on December 22, 2010 our stockholders approved the 2010 Long-Term Incentive Plan (the "2010 Incentive Plan"), which gave us the ability to grant stock options, restricted stock, stock appreciation rights and performance units to employees, directors and consultants, or those who will become employees, directors and consultants of our company and/or our subsidiaries. The 2010 Incentive Plan currently allows for equity awards of up to 4,000,000 shares of common stock. As of March 26, 2019, 175,000 shares of restricted stock outstanding, and no options were outstanding.

Director Compensation

The following table sets forth information concerning cash and non-cash compensation earned by or paid to our directors during the year ended December 31, 2018.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Heung Mei Tsui	16,000	-	-	-	-	-	16,000
Gene Michael Bennett	16,000	-	-	-	-	-	16,000
Yingwen Zhang	6,037	-	-	-	-	-	6,037
Baowen Dong	6,037	-	-	-	-	-	6,037

Our directors will also be reimbursed for all of their out-of-pocket expenses in traveling to and attending meetings of our Board of Directors and committees on which they serve.

Ms. Zhilin Li, our Chairman, President and Chief Executive Officer, was also compensated for serving on our board of directors as set forth in the Summary Compensation Table appearing earlier in this Item 11.

Engagement Letters

On December 5, 2018, we renewed the engagement letters with each of our three independent directors. Pursuant to the renewed engagement letters, entered into on the same terms and conditions as the previous engagement letters and for a term of one year, each of Mr. Zhang and Mr. Dong is entitled to receive annual compensation of RMB40,000 (approximately $5,817), payable quarterly and Mr. Bennett is entitled to receive annual compensation of $16,000, payable quarterly, and a warrant to purchase 5,000 shares of common stock at an exercise price of $0.32 per share. As of the date of this report, no warrants have been issued to Mr. Bennett.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS

The following table sets forth certain information as of March 26, 2019, with respect to the beneficial ownership of our common stock, the sole outstanding class of our voting securities, by (i) any person or group owning more than 5% of each class of voting securities, (ii) each director, (iii) each executive officer and (iv) all executive officers and directors as a group.

As of March 26, 2019, an aggregate of 43,579,557 shares of our common stock were outstanding.

Name and Address of Beneficial Owners(1)(2)	Amount and Nature of Beneficial Ownership	Percent of Class(3)	
Directors and Executive Officers			
Zhilin Li President, Chief Executive Officer, Interim Chief Financial Officer and Chairman of the Board	10,050,000	23.1	%
Heung Mei Tsui Director	9,312,651	21.4	%
Yingwen Zhang Director	0	*	
Gene Michael Bennett (4) Director	0	*	
Baowen Dong Director	0	*	
All directors and executive officers as a group (5 persons)	19,362,651	44.5	%
Greater than 5% Stockholders			
Jian Yang	2,278,815	5.2	%

*

Represents less than 1%.

(1) Pursuant to Rule 13d-3 under the Exchange Act, a person has beneficial ownership of any securities as to which such person, directly or indirectly, through any contract, arrangement, undertaking, relationship or otherwise has or shares voting power and/or investment power or as to which such person has the right to acquire such voting and/or investment power within 60 days.

(2) Unless otherwise stated, each beneficial owner has sole power to vote and dispose of the shares and the address of such person is c/o China Pharma Holdings, Inc., 2nd Floor, No. 17 Jinpan Road, Haikou, Hainan Province, People's Republic of China 570216.

(3) In determining the percentage of common stock owned by the beneficial owners, (a) the numerator is the number of shares of common stock beneficially owned by such owner, including shares the owner may acquire, within 60 days of March 26, 2019, upon the exercise of the options or warrants, if any, held by the owner; and (b) the denominator is the sum of (i) the total 43,579,557 shares of common stock outstanding as of March 26, 2019, and (ii) the number of shares underlying any options or warrants, which such owner has the right to acquire upon the exercise of such options or warrants within 60 days of March 26, 2019 (for those who have options or warrants).

(4) Pursuant to the terms of his engagement letters, Mr. Bennett is entitled to receive warrants to purchase an aggregate of 40,000 shares of our common stock (5,000 shares in each of year between 2008 to 2018 fiscal years). As of the date of this report no such warrants were issued.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Related Party Transactions

Ms. Tsui, one of our directors, has made various loans to the Company. The balance of such loans from Ms. Tsui remained $1,354,567 as of December 31, 2018 and 2017. The loans bear interest at a rate of 1% per annum and principal and interest were payable by December 31, 2018, pursuant to a loans extension confirmation letter executed by the Company and Ms. Tsui. We recognized interest expense of $13,546 for the years ended December 31, 2018 and 2017, respectively.

During 2018, the Company received advances totaling $278,596 from our Chairperson and Chief Executive Officer. This amount is recorded as Other payables – related parties on the accompanying consolidated balance sheets as of December 31, 2018. An aggregate of $87,254 was repaid in January 2019.

Independence of the Board of Directors

The board of directors has determined that Messrs. Gene Michael Bennett, Baowen Dong and Yingwen Zhang are “independent directors” as defined in the listing standards of NYSE American.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

The aggregate fees billed by B F Borgers CPA PC, our principal accountant for professional services rendered for the audit of our annual financial statements included in our Annual Reports on Form 10-K, for the reviews of the financial statements included in our Quarterly Reports on Form 10-Q, and for services in connection with statutory and regulatory filings or engagements were approximately $115,000 for each of the fiscal years ended December 31, 2018 and December 31, 2017.

Audit-Related Fees

We did not incur any audit-related fees during the fiscal years ended December 31, 2018 and 2017.

Tax Fees

We have engaged our current principal accountant to render tax services to us in the year ended December 31, 2017 for $6,000.

All Other Fees

We did not engage our principal accountant to render services to us during the last two fiscal years, other than as reported above.

Pre-Approval Policies and Procedures

Under the Sarbanes-Oxley Act of 2002, all audit and non-audit services performed by our auditors must be approved in advance by our Audit Committee to assure that such services do not impair the auditors' independence from us. In accordance with its policies and procedures, the Audit Committee pre-approved the audit service performed by B F Borgers CPA PC, for our consolidated financial statements as of and for the year ended December 31, 2018.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

Financial Statements

The following financial statements of China Pharma Holdings, Inc. and Reports of Independent Registered Public Accounting Firm are presented in the "F" pages of this report:

(b) Exhibits

See the Exhibit Index following the signature page of this report, which is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 28, 2019 CHINA PHARMA HOLDINGS, INC.

By: /s/ Zhilin Li
Name: Zhilin Li
Title: Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Zhilin Li Zhilin Li	Chairman of the Board, President, Chief Executive Officer (principal executive officer) and interim Chief Financial Officer (principal financial officer and principal accounting officer)	March 28, 2019
/s/ Heung Mei Tsui Heung Mei Tsui	Director	March 28, 2019
/s/ Gene Michael Bennett Gene Michael Bennett	Director	March 28, 2019
/s/ Yingwen Zhang Yingwen Zhang	Director	March 28, 2019
/s/ Baowen Dong	Director	March 28, 2019

Baowen Dong

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CHINA PHARMA HOLDINGS, INC.

Exhibit Index to Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2018

Exhibit No.	**Description**
3.1	Articles of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on December 31, 2012).
3.2	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on December 31, 2012).
10.1*	Offer Letter dated December 12, 2018 from the Company and accepted by Ms. Heung Mei Tsui for Ms. Tsui serving as a director of the Company.
10.2*	Offer Letter dated December 12, 2018 from the Company and accepted by Ms. Zhilin Li for Ms. Li serving as a director of the Company.
10.3	Form of Independent Director Offer Letter (incorporated by reference to Exhibit 10.2 to our Annual Report on Form 10-K filed on March 30, 2015).
10.4	Employment Agreement dated July 1, 2015 between Hainan Helpson Medical & Biotechnology Co., Ltd. and Zhilin Li (incorporated by reference to Exhibit 10.1 to our Annual Report on Form 10-K filed on March 30, 2016).
10.5*	Loans Extension Confirmation Letter between the Company and Heung Mei Tsui confirming the extension of the loans.
10.6	2010 Long-Term Incentive Plan of the Company (incorporated by reference to the Definitive Proxy Statement on Schedule 14A filed on November 12, 2010).
10.7	Form of Restricted Stock Grant Agreement between the Company and the grantees under 2010 Long-Term Incentive Plan of the Company (incorporated by reference to our Current Report on Form 8-K filed on June 1, 2011).
10.8	Form of Non-Qualified Stock Option Grant Agreement between the Company and the grantees under 2010 Long-Term Incentive Plan of the Company (incorporated by reference to our Current Report on Form 8-K filed on June 1, 2011).
14.1	

	Code of Business Conduct and Ethics (incorporated by reference to the Registration Statement on Form S-1 filed on July 11, 2008).
21.1	Subsidiaries of the Company (incorporated by reference to our Annual Report on Form 10-K filed on March 3, 2011).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Exchange Act.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Exchange Act.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive data files pursuant to Rule 405 of Regulation S-T

*Exhibits filed herewith.

CHINA PHARMA HOLDINGS, INC. AND SUBSIDIARIES

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of China Pharma Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of China Pharma Holdings, Inc. and its subsidiaries (collectively the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as

evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ B F Borgers CPA PC

We have served as the Company’s auditor since 2016.

Lakewood, Colorado

March 28, 2019

CHINA PHARMA HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,186,587	$ 2,030,214
Restricted cash	1,273,940	709,796
Banker's acceptances	20,579	39,867
Trade accounts receivable, less allowance for doubtful accounts of $17,815,075 and $18,209,734, respectively	916,931	2,293,120
Other receivables, less allowance for doubtful accounts of $34,884 and $40,010, respectively	170,098	162,981
Advances to suppliers	47	461,307
Inventory	5,054,975	6,407,155
Prepaid expenses	123,759	185,647
Total Current Assets	8,746,916	12,290,087
Advances for purchases of intangible assets	17,069,587	23,722,954
Property, plant and equipment, net	19,294,379	23,541,003
Intangible assets, net	266,443	398,856
TOTAL ASSETS	$ 45,377,325	$ 59,952,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Trade accounts payable	$ 1,060,934	$ 1,141,138
Accrued expenses	310,804	276,368
Other payables	3,065,508	2,858,701
Advances from customers	525,647	581,132
Other payables - related parties	1,633,263	1,354,567
Current portion of construction loan facility	2,181,360	2,305,430
Bankers' acceptance notes payable	1,273,940	709,796
Total Current Liabilities	10,051,456	9,227,132
Non-current Liabilities:		
Construction loan facility	4,362,720	6,916,291
Deferred tax liability	764,374	738,175
Total Liabilities	15,178,550	16,881,598
Commitments and Contingencies (Note 12)		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	-	-
	43,580	43,580

Common stock, $0.001 par value; 95,000,000 shares authorized; 43,579,557 shares and 43,579,557 shares outstanding, respectively		
Additional paid-in capital	23,590,204	23,590,204
Retained (deficit) earnings	(5,270,358)	5,479,809
Accumulated other comprehensive income	11,835,349	13,957,709
Total Stockholders' Equity	30,198,775	43,071,302
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 45,377,325	$ 59,952,900

The accompanying notes are an integral part of these consolidated financial statements.

CHINA PHARMA HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE INCOME (LOSS)

	For the Years Ended December 31,	
	2018	2017
Revenue	$12,330,687	$13,212,314
Cost of revenue	10,355,839	10,743,764
Gross profit	1,974,848	2,468,550
Operating expenses:		
Selling expenses	3,216,512	3,460,596
General and administrative expenses	1,949,921	2,019,949
Research and development expenses	172,384	90,474
Bad debt expense	604,388	1,393,576
Impairment of long term assets	6,479,057	14,183,969
Total operating expenses	12,422,262	21,148,564
Loss from operations	(10,447,414)	(18,680,014)
Other income (expense):		
Interest income	38,516	64,414
Interest expense	(451,258)	(539,334)
Net other expense	(412,742)	(474,920)
Loss before income taxes	(10,860,156)	(19,154,934)
Income tax benefit (expense)	109,989	(122,631)
Net loss	(10,750,167)	(19,277,565)
Other comprehensive income - foreign currency translation adjustment	(2,122,360)	3,439,733
Comprehensive income (loss)	$(12,872,527)	$(15,837,832)
Loss per share:		
Basic and diluted	$(0.25)	$(0.44)
Weighted average shares outstanding	43,579,557	43,579,557

The accompanying notes are an integral part of these consolidated financial statements.

CHINA PHARMA HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Retained Earnings	**Accumulated Other Comprehensive**	**Total Stockholders'**
	Shares	Amount	Capital	(deficit)	Income	Equity
Balance, December 31, 2016	43,579,557	$43,580	$23,590,204	$24,757,374	$ 10,517,976	$58,909,134
Net loss for the year				(19,277,565)		(19,277,565)
Foreign currency translation adjustment					3,439,733	3,439,733
Balance, December 31, 2017	43,579,557	43,580	23,590,204	5,479,809	13,957,709	43,071,302
Net loss for the year				(10,750,167)		(10,750,167)
Foreign currency translation adjustment					(2,122,360)	(2,122,360)
Balance, December 31, 2018	43,579,557	$43,580	$23,590,204	$(5,270,358)	$ 11,835,349	$30,198,775

The accompanying notes are an integral part of these consolidated financial statements.

CHINA PHARMA HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2018	2017
Cash Flows from Operating Activities:		
Net loss	$(10,750,167)	$(19,277,565)
Depreciation and amortization	3,258,739	3,291,330
Inventory write off	954,311	118,003
Bad debt expense	604,388	1,393,576
Deferred income taxes	68,419	122,631
Impairment of long term assets	6,479,057	14,183,969
Changes in assets and liabilities:		
Trade accounts and other receivables	99,400	51,024
Advances to suppliers	(449,101)	1,614,958
Inventory	688,852	1,718,336
Trade accounts payable	(16,441)	(2,045,948)
Accrued taxes payable	(147,099)	18,753
Other payables and accrued expenses	437,901	420,523
Advances from customers	(25,127)	(274,068)
Prepaid expenses	53,860	(494,306)
Net Cash Provided by Operating Activities	1,256,992	841,216
Cash Flows from Investing Activities:		
Purchases of property and equipment	(51,145)	(136,479)
Net Cash Used in Investing Activities	(51,145)	(136,479)
Cash Flows from Financing Activities:		
Payments of construction term loan	(2,263,877)	(1,479,944)
Advances from related party	287,423	-
Net Cash Used in Financing Activities	(1,976,454)	(1,479,944)
Effect of Exchange Rate Changes on Cash	(73,020)	139,619
Net Decrease in Cash and Cash Equivalents	(843,627)	(635,588)
Cash and Cash Equivalents at Beginning of Period	2,030,214	2,665,802
Cash and Cash Equivalents at End of Period	$1,186,587	$2,030,214
Supplemental Cash Flow Information:		
Cash paid for income taxes	$-	$-
Cash paid for interest	$588,191	$525,788

Supplemental Noncash Investing and Financing Activities:

Issuance of banker's acceptances	$625,128	$709,796
Accounts receivable collected with banker's acceptances	579,896	531,294
Inventory purchased with banker's acceptances	597,686	492,906

The accompanying notes are an integral part of these consolidated financial statements.

CHINA PHARMA HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2018 AND 2017

NOTE 1 – ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization and Nature of Operations – China Pharma Holdings, Inc., a Nevada corporation, owns 100% of Onny Investment Limited (Onny), a British Virgin Islands corporation, which owns 100% of Hainan Helpson Medical & Biotechnology Co., Ltd (Helpson), a company organized under the laws of the People's Republic of China (the PRC). China Pharma Holdings, Inc. and its subsidiaries are referred to herein as the Company.

On December 31, 2012, China Pharma Holdings, Inc. consummated a reincorporation merger for the purpose of changing its state of incorporation from Delaware to Nevada, pursuant to the terms and conditions of an Agreement and Plan of Merger dated December 27, 2012. The reincorporation merger was approved by stockholders holding the majority of the Company's outstanding shares of common stock on December 21, 2012.

The Foreign Investment Industrial Catalogue (the "Catalogue") jointly issued by China's Ministry of Commerce and the National Development and Reform Commission (the latest version is the 2012 version, effective January 30, 2012) classified various industries/businesses into three different categories: (i) encouraged for foreign investment; (ii) restricted to foreign investment; and (iii) prohibited from foreign investment. For any industry/business not covered by any of these three categories, they will be deemed industries/businesses permitted for foreign investment. A typical foreign investment restriction in the pharmaceutical industry is that a foreign investment enterprise (the "FIE") shall not have the whole or majority of its equity interests held by a foreign owner if the FIE establishes more than 30 branch stores and distributes a variety of brands in those franchise stores. However, the Company's business is not subject to this restriction.

Helpson manufactures and markets generic and branded pharmaceutical products as well as biochemical products primarily to hospitals and private retailers located throughout the PRC. The Company believes Helpson's business is not subject to any ownership restrictions prescribed under the Catalogue. Onny acquired 100% of the ownership in Helpson on May 25, 2005, by entering into an Equity Transfer Agreement with Helpson's three former shareholders. The transaction was approved by the Commercial Bureau of Hainan Province on June 12, 2005 and Helpson received the Certificate of Approval for Establishment of Enterprises with Foreign Investment in the PRC on the same day. Helpson received its business license evidencing its WFOE (Wholly Foreign Owned Enterprise) status on June 21, 2005.

The Company has acquired and continues to acquire well-accepted medical formulas to add to its diverse portfolio of Western and Chinese medicines.

Consolidation and Basis of Presentation – The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and are expressed in United States dollars. The accompanying consolidated financial statements include the accounts and operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in the consolidation.

Helpson's functional currency is the Chinese Renminbi. Helpson's revenue and expenses are translated into United States dollars at the average exchange rate for the period. Assets and liabilities are translated at the exchange rate as of the end of the reporting period. Gains or losses from translating Helpson's financial statements are included in accumulated other comprehensive income, which is a component of stockholders' equity. Gains and losses arising from transactions denominated in a currency other than the functional currency of the entity that is party to the transaction are included in the results of operations.

Accounting Estimates **-** The methodology used to prepare for the Company's financial statements is in conformity with the accounting principles generally accepted in the United States of America, which requires the management of the Company ("Management") to make estimates and assumptions that affect: (1) the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the financial statements; and (2) the reported amounts of revenues and expenses during the reporting periods. Therefore, actual results could differ from those estimates.

Cash and Cash Equivalents – Cash and cash equivalents include interest bearing and non-interest bearing bank deposits, money market accounts, and short-term banker's acceptances notes purchased with maturities of three months or less.

Restricted Cash –Restricted cash includes cash that has been deposited with a bank to satisfy outstanding obligations under banker's acceptance notes issued by the Company as discussed in Note 7.

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Trade Accounts Receivable and Allowance for Doubtful Accounts – Trade accounts receivables are carried at the original invoiced amounts, less an allowance for doubtful accounts. The allowances for doubtful accounts are calculated based on a detailed review of certain individual customer accounts and an estimation of the overall economic conditions affecting the Company's customer base. The Company reviews a customer's credit history before extending credit to the customer. If the financial condition of its customers were to deteriorate, resulting in an impairment of their ability to make payments, additions to the allowance would be required. A provision is made against accounts receivable to the extent they are considered unlikely to be collected. Charges to bad debt expense totaled $604,388 and $1,393,576 for the years ended December 31, 2018 and 2017, respectively.

Trade accounts receivable that have been fully allowed for and determined to be uncollectible are charged against the allowance in the period the determination is made. The Company charged off uncollectible trade accounts receivable balances in the amount of $0 against the allowance for the years ended December 31, 2018 and 2017, respectively. It is common practice in the PRC for receivables to extend beyond one year. Customer balances outstanding for more than one year are allowed for at a greater rate when calculating the allowance for doubtful accounts.

Advances to Suppliers and Advances from Customers – Common practice in the PRC is to make advances to suppliers for materials and to receive advances from customers for finished products. Advances to suppliers are applied to trade accounts payable when the materials are received. Advances received from customers are applied against trade accounts receivable when finished products are sold. The Company reviews a supplier's credit history and background information before advancing a payment. If the financial condition of its suppliers were to deteriorate, resulting in an impairment of their ability to deliver goods or provide services, the Company would recognize bad debt expenses in the period they are considered unlikely to be collected.

Inventory – Inventory consists of raw materials, work in process and finished goods and is stated at the lower of cost or net realizable value. Cost is determined using a weighted average. For work in process and manufactured inventories, cost consists of raw materials, direct labor and an allocated portion of the Company's production overhead. The Company writes down excess and obsolete inventory to its estimated net realizable value based upon assumptions about future demand and market conditions. For finished goods and work in process, if the estimated net realizable value for an inventory item, which is the estimated selling price in the ordinary course of business, less reasonably predicable costs to completion and disposal, is lower than its cost, the specific inventory item is written down to its estimated net realizable value. Net realizable value for raw materials is based on replacement cost. Provisions for inventory write-downs are included in the cost of revenues in the consolidated statements of operations. Inventories are carried at this lower cost basis until sold or scrapped.

Valuation of Long-Lived Assets – The carrying values of long-lived assets are reviewed annually for impairment or whenever events or changes in circumstances indicate that the carrying values may not be recoverable. When such an event occurs, the Company projects the undiscounted cash flows to be generated from the use of the asset and its eventual disposition over the remaining life of the asset. If projections indicate that the carrying value of an asset will not be recovered, it is reduced by the estimated excess of the carrying value over the projected discounted cash flows estimated to be generated by the asset. If there is uncertainty both in timing and amount, the Company will use the projected discounted cash flows to be generation by the asset. For the years ended December 31, 2018 and 2017 the Company evaluated its long-lived assets and determined that necessary impairment adjustments were $6,479,057 and $14,183,969, respectively. In 2018, the amount is comprised of $344,786 related to the impairment of certain advances to suppliers and $6,134,271 was related to advances for intangible assets. In 2017, the amount is comprised of $548,156 related to the impairment of certain prepaid expenses and $13,635,813 was related to advances for intangible assets.

Property and Equipment – Property and equipment are stated at cost. Maintenance and repairs are charged to expenses as incurred and major improvements are capitalized. Gains or losses on sale, trade-in or retirement are included in operations during the period of disposition. Depreciation relating to office equipment was included in general and administrative expenses, while all other depreciation was included in cost of revenue.

Revenue Recognition – Revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration that an entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods in the contract; (ii) determination of whether the promised goods are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations the Company must deliver and which of these performance obligations are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company’s performance obligations are transferred to customers at a point in time, typically upon buyer’s designated carrier or the buyer picks up the goods at our warehouse.

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For all reporting periods, the Company has not disclosed the value of unsatisfied performance obligations for all product revenue contracts with an original expected length of one year or less, which is an optional exemption that is permitted under the adoption rules.

Cost of Revenues – Cost of revenues includes wages, materials, depreciation, handling charges, and other expenses associated with the manufacture and delivery of products.

Research and Development – Research and development expenditures are recorded as expenses in the period in which they occur.

Basic and Diluted Loss per Common Share - Basic loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted loss per share is calculated to give effect to potentially issuable dilutive common shares.

There were no potentially dilutive common shares outstanding during the years ended December 31, 2018 and 2017, respectively.

Credit Risk – The carrying amount of accounts receivable included in the consolidated balance sheet represents the Company's exposure to credit risk in relation to its financial assets. No other financial asset carries a significant exposure to credit risk. The Company performs ongoing credit evaluations of each customer's financial condition. The Company maintains allowances for doubtful accounts and such allowances in the aggregate have not exceeded Management's estimates.

The Company has its cash in bank deposits primarily at state owned banks located in the PRC. Historically, deposits in PRC banks have been secured due to the state policy of protecting depositors' interests. The PRC promulgated a Bankruptcy Law in August 2006, effective June 1, 2007, which contains provisions for the implementation of measures for the bankruptcy of PRC banks. In the event that bankruptcy laws are enacted for banks in the PRC, the

Company’s deposits may be at a higher risk of loss.

Interest Rate Risk – The Company is exposed to the risk arising from changing interest rates, which may affect the ability of repayment of existing debts and the viability of securing future debt instruments within the PRC.

Recent Accounting Pronouncements

Recently Issued Pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases*, a new standard on accounting for leases. The ASU introduces a lessee model that brings most leases onto the balance sheet. The new standard also aligns many of the underlying principles of the new lessor model with those in the current accounting guidance as well as the FASB’s new revenue recognition standard. However, the ASU eliminates the use of bright-line tests in determining lease classification as required in the current guidance. The ASU also requires additional qualitative disclosures along with specific quantitative disclosures to better enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The pronouncement is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, using a modified retrospective approach. Early adoption is permitted. The Company does not believe the pronouncement will have a material impact on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, which introduces new guidance for the accounting for credit losses on instruments within its scope. The new guidance introduces an approach based on expected losses to estimate credit losses on certain types of financial instruments. It also modifies the impairment model for available-for-sale (AFS) debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. The pronouncement will be effective for public business entities that are SEC filers in fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early application of the guidance will be permitted for all entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company anticipates recording lease assets and liabilities of approximately $0.2 million, with no material impact to its consolidated statement of income and comprehensive income. However, the ultimate impacts of adopting ASU 2016-02 will depend on the Company's lease portfolio as of the adoption date.

From time to time, the FASB or other standards setting bodies issue new accounting pronouncements. Updates to the FASB ASCs are communicated through issuance of ASUs. Unless otherwise discussed, the Company believes that the recently issued guidance, whether adopted or to be adopted in the future, is not expected to have a material impact on its consolidated financial statements upon adoption.

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NOTE 2 – INVENTORY

Inventory consisted of the following:

	December 31, 2018	December 31, 2017
Raw materials	$ 3,148,990	$ 4,733,679
Work in process	493,768	481,863
Finished goods	1,412,217	1,191,613
Total Inventory	$ 5,054,975	$ 6,407,155

The Company wrote off obsolete inventory totaling $954,311 and $118,003 for the years ending December 31, 2018 and 2017, respectively.

NOTE 3 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	December 31, 2018	**December 31, 2017**
Permit of land use	$409,612	$432,910
Building	9,511,832	10,052,840
Plant, machinery and equipment	26,576,409	28,044,515
Motor vehicle	312,807	330,598
Office equipment	198,292	200,974
Total	37,008,952	39,061,837
Less: accumulated depreciation	(17,714,573)	(15,520,834)

Property, plant and equipment, net	$19,294,379	$23,541,003

Depreciation is computed on a straight-line basis over the estimated useful lives of the assets as follows:

Asset	**Life - years**
Permit of land use	40 - 70
Building	20 - 49
Plant, machinery and equipment	5 - 10
Motor vehicle	5 - 10
Office equipment	3-5

Depreciation relating to office equipment was included in general and administrative expenses, while all other depreciation was included in cost of revenue. For the years ended December 31, 2018 and 2017, depreciation expense was $3,143,596 and $3,125,937, respectively.

NOTE 4 - INTANGIBLE ASSETS

Intangible assets represent the cost of medical formulas approved for production by the China Food and Drug Administration (“CFDA”). The Company did not obtain CFDA production approval for any medical formulas during the years ended December 31, 2018 and 2017, and no costs were reclassified from advances to intangible assets during the years ended December 31, 2018 and 2017, respectively.

Approved medical formulas are amortized from the date CFDA approval is obtained over their individually identifiable estimated useful lives, which range from ten to thirteen years. It is at least reasonably possible that a change in the estimated useful lives of the medical formulas could occur in the near term due to changes in the demand for the drugs and medicines produced from these medical formulas. Amortization expense relating to intangible assets was $115,143 and $165,394, respectively for the years ended December 31, 2018 and 2017, and was included in the general and administrative expenses. Medical formulas typically do not have a residual value at the end of their amortization period.

The Company evaluates each approved medical formula for impairment at the date of CFDA approval, when indications of impairment are present and also at the date of each financial statement. The Company’s evaluation is based on an estimated undiscounted net cash flow model, which considers currently available market data for the related drug and the Company’s estimated market share. If the carrying value of the medical formula exceeds the estimated future net cash flows, an impairment loss is recognized for the excess of the carrying value over the fair value of the medical formula, which is determined by the estimated discounted future net cash flows. No impairment loss was recognized during the years ended December 31, 2018 and 2017.

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Intangible assets consisted solely of CFDA approved medical formulas as follows:

	December 31, 2018	December 31, 2017
Gross carrying amount	$ 4,909,318	$ 5,188,547
Accumulated amortization	(4,642,875)	(4,789,691)
Net carrying amount	$ 266,443	$ 398,856

The estimated aggregate annual amortization expense for each of the next five years and thereafter is as follows:

Year	Amount
2019	60,038
2020	37,112
2021	37,112
2022	37,112
2023	37,112
Thereafter	57,957
Total	$266,443

NOTE 5 – ADVANCES FOR PURCHASES OF INTANGIBLE ASSETS

In order to expand the number of medicines the Company manufactured and marketed, it entered into contracts with independent laboratories and others for the purchase of medical formulas. Although CFDA approval had not been obtained for these medical formulas at the dates of the respective contracts, the objective of the contracts was for the Company to purchase CFDA-approved medical formulas once the CFDA approval process is completed. The Company received the titles to two patents that relate to medical formulas currently in the CFDA approval process for the year ended December 31, 2013. These patents are not expired.

Prior to entering into contracts with the Company, laboratories are typically required to complete all research and development to determine the content of the medical formula and the method to produce the generic medicine. The application to the CFDA for production approval must be made by the production facility that will produce the related product. As a result, a contract typically provides that the Company buys the medical formula from the laboratory and the laboratory is required to assist the Company in applying for and obtaining the production approval from the CFDA.

In order to promote the standard of the pharmaceutical industry in China in line with international standards, significant changes have taken place in the policies and regulations in this industry in recent years. A series of policies on consistency evaluation and drug review process have been issued, and more potential reforms and adjustments are underway. In this context, the Company believes that the uncertainties in the timetables for obtaining CFDA production approvals for products under research are increasing.

Under the new regulations and policy environment, the criteria for formulations' development are more stringent. The Company must supplement and improve the corresponding processes and standards to meet the latest requirements of CFDA in accordance with the requirements of consistency evaluation. As a result, the Company anticipates an extended timeline on the approval process of our current pipeline products.

Under the terms of the contracts, the laboratories are required to assist the Company in obtaining production approval for the medical formulas from the CFDA. Management monitors the status of each medical formula on a regular basis in order to assess whether the laboratories are performing adequately under the contracts. If a medical product is not approved by the CFDA, as evidenced by their issuance of a denial letter, or if the laboratory breaches the contract, the laboratory is required under the contract to provide a refund to the Company of the full amount of the payments made to the laboratory for that formula, or the Company can require the application of those payments to another medical formula with the same laboratory. As a result of the refund right, the Company is ultimately purchasing an approved medical product. Accordingly, payments made prior to the issuance of production approval by the CFDA are recorded as advances for purchases of intangible assets.

To date, no formula has failed to receive CFDA production approval nor has the Company been informed or been made aware of any formula that may fail to receive such approval. However, there is no assurance that the medical products will receive production approval, and if the Company does not receive such approval, it will enforce its contractual rights to receive a refund from the laboratory or have the payments applied to another medical formula with the same laboratory.

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As of December 31, 2018, the Company was obligated to pay laboratories and others approximately $0.30 million upon the completion of various phases of contracts to obtain CFDA production approval of medical formulas.

During the year ended December 31, 2018, the Company reviewed the contracts relating to advances made for purchases of intangible assets with independent laboratories and determined that the advances made by the Company for two formulas to two laboratories were impaired. In 2017, four formulas to three of the independent laboratories were impaired. As a result, the Company recognized an impairment loss for the advances made to these laboratories for the years ended December 31, 2018 and 2017 in the amount of $6,134,271 and $13,635,813, respectively.

NOTE 6 – RELATED PARTY TRANSACTIONS

A member of the Company's board of directors ("Board") had previously advanced the Company an aggregate amount of $1,354,567 as of December 31, 2018 and 2017, which is recorded as Other payables – related parties on the accompanying consolidated balance sheets. The advances bear interest at a rate of 1.0% per year. Total interest expense for each of the years ended December 31, 2018 and 2017 was $13,546.

During 2018, the Company received advances totaling $278,696 from our Chairperson, Chief Executive Officer and Interim Chief Financial Officer. This amount is recorded as Other payables – related parties on the accompanying consolidated balance sheets as of December 31, 2018. An aggregate of $87,254 was repaid in January 2019. Compensation payable to our Chairperson, Chief Executive Officer and Interim Chief Financial Officer is included in Other payables in the accompanying consolidated balance sheet totaling $2,051,186 and $1,815,186 as of December 31, 2018 and 2017, respectively.

NOTE 7 – BANKER'S ACCEPTANCE NOTES PAYABLE

In March 2017 the Company entered into a Banker's Acceptance Note Agreement with a bank. Pursuant to the terms of the agreement, the Company can issue banker's acceptance notes to any third party as payment of amounts owing to

that third party. The Company is required to deposit with the bank an amount equal to the amounts represented by the banker's acceptance notes issued to the third parties. The amount of these deposited balances is shown as "Restricted cash" on the accompanying balance sheets as of December 31, 2018 and 2017. The maximum amount that the Company can issue under this agreement is limited to the lesser of RMB30,000,000 (approximately $4.5 million) or the amount of cash available to deposit against the banker's acceptance notes. In addition, the agreement calls for the payment of fees equal to 0.05% of the note amount to the bank. As of December 31, 2018 and 2017, the Company had outstanding banker's acceptance notes in the amount of $1,273,940 and $709,796, respectively.

NOTE 8 – CONSTRUCTION LOAN FACILITY

The Company obtained a construction loan facility, dated June 21, 2013, in the aggregate amount of RMB 80,000,000 (approximately $13 million). The loan facility is for an eight-year term, which commenced on July 11, 2013, the initial draw-down date. The proceeds of the loan were used for and are collateralized by the construction of the Company's new production facility and the included production line equipment and machinery. The loan bears interest based upon 110% of the PRC government's eight-year term rate effective on the actual draw-down date, subject to annual adjustments based on 110% of the floating rate for the same type of loan on the anniversary from the draw-down date and its subsequent anniversary dates. On July 10, 2016, 2017 and 2018 the interest rate was adjusted to 5.39%, 5.39% and 5.39%, respectively. The loan required interest only payments for the first two years. Beginning July 11, 2015, the balance of the principal was due in at least two (2) annual installments with the first annual payment being due within the six month period after July 10, 2015 and the second annual payment being due July 10, 2016 and each following year over the next five years through July 11, 2022 on the identical terms as described above for 2015. The Company has made all required payments due under the loan. As of December 31, 2018, the Company had no additional amounts available to it under this facility. During the year ended December 31, 2018, the Company made principal payments in the amount of $2,030,214 (RMB 15,000,000).

Principal payments required for the remaining term of the loan facility as of December 31, 2018 are as follows:

Year	Amount
2019	2,181,360
2020	2,181,360
2021	2,181,360
	$6,544,080

Fair Value of Construction Loan Facility – Based on the borrowing rates currently available to the Company for bank loans with similar terms and maturities, the carrying amounts of the construction loan facility outstanding as of December 31, 2018 and 2017 approximated its fair value because the underlying instrument bears an interest rate that approximated current market rates.

CHINA PHARMA HOLDINGS, INC.

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NOTE 9 - INCOME TAXES

Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which temporary differences are expected to be recovered or settled. The effect of a change in tax laws or rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

Liabilities are established for uncertain tax positions expected to be taken in income tax returns when such positions are judged to meet the “more-likely-than-not” threshold based on the technical merits of the positions. Estimated interest and penalties related to uncertain tax positions are included as a component of other expenses. Through December 31, 2018, the Company has not identified any uncertain tax positions that it has taken. U.S. income tax returns for the years ended December 31, 2015 through December 31, 2018 and the Chinese income tax return for the year ended December 31, 2018 are open for possible examination.

On March 16, 2007, the National People’s Congress of China passed the Enterprise Income Tax Law (EIT Law) and on December 6, 2007, the State Council of China issued the Implementation Regulations for the EIT Law, which took effect on January 1, 2008. The EIT Law and Implementation Regulations Rules impose a unified EIT of 25% on all domestic-invested enterprises and Foreign Invested Entities, or FIEs, unless they qualify under certain limited exceptions.

The Company is located in a special region, which had a 15% corporate income tax rate before the new EIT Law. The new EIT Law abolished the preferential corporate income tax rate in the special region. The Company transitioned to the new 25% tax rate over a five year period which began on January 1, 2008. During 2010, the Company applied for and received a favorable tax rate of 15% for fiscal 2011 through 2013 due to its status in the PRC as a high technology enterprise. In 2013, the Company again applied for and received the same favorable tax rate for 2014 to 2016. The recent net losses have put the Company in an unfavorable position for the potential renewal of “National High-Tech Enterprise” status in 2017. After evaluating the feasibility of the renewal, the Company has decided not to renew this status. Under the current tax law in the PRC, the Company is and will be subject to the enterprise income tax rate of 25%.

The provision for income taxes consisted of the following:

	Years Ended December 31,	
	2018	**2017**
Current	$(178,408)	$-
Deferred	68,419	122,631
Total income tax expense	$(109,989)	$122,631

Following is a reconciliation of income taxes calculated at the federal statutory rates to the provision for income taxes:

	Years Ended December 31,	
	2018	**2017**
(Benefit) tax at statutory rate of 25%	$(2,715,040)	$(4,788,734)
Prior year refund received	(178,408)	-
Other, primarily the difference in U.S. tax rates	7,881	8,077
Change in valuation allowance	2,775,578	4,903,288
Income tax (benefit) expense	$(109,989)	$122,631

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The temporary differences which give rise to the deferred income tax assets and liability are as follows:

	December 31, 2018	2017
Deferred income tax assets:		
Allowance for doubtful trade receivables	$4,453,769	$4,552,432
Allowance for doubtful other receivables	8,721	10,002
Inventory obsolescence reserve	1,487,087	1,595,671
Expenses not deductible in current year	1,101,268	1,076,126
Advances for intangible assets impairment	5,628,803	4,387,237
PRC net operating loss carry forward	13,124,191	14,572,439
U.S. net operating loss carry forward	1,187,112	1,076,830
Total deferred income tax assets	26,990,951	27,270,737
Valuation allowance	(26,990,951)	(27,270,737)
Net deferred income tax asset	$-	$-
Deferred income tax liability:		
Intangible assets	$764,374	$738,175

As of December 31, 2018, the Company had net operating loss carryforwards for PRC tax purposes of approximately $52.5 million, which are available to offset any future taxable income through 2023. Approximately $6.1 million of these carryforwards expired in 2018. Approximately $3.9 million of the remaining carryforwards will expire in 2019. During 2018, the Company received a refund related to its 2013 PRC tax return in the amount of $178,408.

The Company also has net operating losses for United States federal income tax purposes of approximately $5.7 million which are available to offset future taxable income, if any, through 2038.

Recent U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (the “U.S. Tax Reform”), was signed into law on December 22, 2017. The U.S. Tax Reform significantly modified the U.S. Internal Revenue Code by, among other things, reducing the statutory U.S. federal corporate income tax rate from 35% to 21% for taxable years beginning after December 31, 2017; limiting and/or eliminating many business deductions; migrating the U.S. to a territorial tax system with a one-time transition tax on a mandatory deemed repatriation of previously deferred foreign earnings of certain foreign subsidiaries; subject to certain limitations, generally eliminating U.S. corporate

income tax on dividends from foreign subsidiaries; and providing for new taxes on certain foreign earnings. Taxpayers may elect to pay the one-time transition tax over eight years, or in a single lump-sum payment. The decrease in the United States federal corporate income tax rate from 34% to 21% for 2018 decreased the valuation allowance related to the U.S. net operating losses by approximately $667,000 at December 31, 2017. There was no liability at December 31, 2018 and 2017 for the mandatory deemed repatriation tax.

In assessing the likelihood of realization of deferred tax assets, Management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those differences become deductible or tax loss carry forwards are utilized. Management considers projected future taxable income and tax planning strategies in making this assessment. Based upon an assessment of the level of historical taxable income and projections for future taxable income over the periods on which the deferred tax assets are deductible or can be utilized, Management believes it is not likely for the Company to realize all benefits of the deferred tax assets as of December 31, 2018 and 2017. Therefore, the Company provided for a valuation allowance against its deferred tax assets of $26,990,951 and $27,270,737 as of December 31, 2018 and 2017, respectively.

The Company also incurred various other taxes, comprised primarily of business taxes, value-added taxes, urban construction taxes, education surcharges and others. Any unpaid amounts are reflected on the balance sheets as accrued taxes payable.

NOTE 10 – FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. To measure fair value, a hierarchy has been established which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs. This hierarchy uses three levels of inputs to measure the fair value of assets and liabilities as follows: Level 1 – Quoted prices in active markets for identical assets or liabilities; Level 2 – Observable inputs other than Level 1 including quoted prices for similar assets or liabilities, quoted prices in less active markets, or other observable inputs that can be corroborated by observable market data; and Level 3 – Unobservable inputs supported by little or no market activity for financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

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The Company uses fair value to measure the value of the banker's acceptance notes it holds. The banker's acceptance notes are recorded at cost which approximates fair value. The Company held the following assets and liabilities recorded at fair value:

Description	December 31, 2018	Fair Value Measurements at Reporting Date Using Level 1	Level 2	Level 3
Banker's acceptance notes	$ 20,579	$ -	$20,579	$ -
Total	$ 20,579	$-	$20,579	$-

Description	December 31, 2017	Fair Value Measurements at Reporting Date Using Level 1	Level 2	Level 3
Banker's acceptance notes	$ 39,867	$ -	$39,867	$ -
Total	$ 39,867	$-	$39,867	$-

NOTE 11 - STOCKHOLDERS' EQUITY

The Company is authorized to issue 95,000,000 shares of common stock, $0.001 par value, and 5,000,000 shares of preferred stock, $0.001 par value. The preferred stock may be issued in series with such designations, preferences, stated values, rights, qualifications or limitations as determined solely by the Company's Board.

Employee Stock Options

2010 Incentive Plan

On November 12, 2010, the Company's Board of Directors adopted the Company's 2010 Incentive Plan (the "Plan"), which was then approved by stockholders on December 22, 2010. The Plan gave the Company the ability to grant stock options, restricted stock, stock appreciation rights and performance units to its employees, directors and consultants, or those who will become employees, directors and consultants of the Company and/or its subsidiaries. The Plan currently allows for equity awards of up to 4,000,000 shares of common stock. Through December 31, 2018, there were 175,000 shares of restricted stock granted and outstanding under the Plan. No options were outstanding as of December 31, 2018 under the Plan.

There were no securities issued from the Plan during each of the years ended December 31, 2018 and 2017.

The Company recognized no compensation expense related to the awards of common shares and the grants and modifications of stock options during each of the years ended December 31, 2018 and 2017.

The fair value of each option award is estimated on the date of grant using the Black-Scholes Option Pricing Model. Expected volatility is based on the historical volatility of the Company's common stock prices. The Company uses historical data to estimate employee termination rates. The expected term of options granted is determined by the simplified method, which is one-half of the original contractual term. The simplified method is used due to the lack of historical share option exercise data to provide a reasonable basis upon which to estimate expected term. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

As of December 31, 2018, there was no remaining unrecognized compensation expense related to stock options or restricted stock grants.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2018 AND 2017

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Economic environment **-** Substantially all of the Company's operations are conducted in the PRC, and therefore the Company is subject to special considerations and significant risks not typically associated with companies operating in the United States of America. These risks include, among others, the political, economic and legal environments and fluctuations in the foreign currency exchange rate. The Company's results from operations may be adversely affected by changes in the political and social conditions in the PRC, and by changes in governmental policies with respect to laws and regulations, anti-inflationary measures, currency conversion and remittance abroad, and rates and methods of taxation, among other things. The unfavorable changes in global macroeconomic factors may also adversely affect the Company's operations.

In addition, all of the Company's revenue is denominated in the PRC's currency of Renminbi (RMB), which must be converted into other currencies before remittance out of the PRC. Both the conversion of RMB into foreign currencies and the remittance of foreign currencies abroad require approval of the PRC government.

NOTE 13 – CONCENTRATIONS

For the year ended December 31, 2018, no customer accounted for more than 10% of sales and two customers accounted for 49.1% and 10.6% of accounts receivable. Three suppliers accounted for 26.2%, 17.0% and 11.2% of raw material purchases, and three different products accounted for 33%, 20% and 18% of revenue.

For the year ended December 31, 2017, no customer accounted for more than 10.0% of sales and four suppliers accounted for 19.8%, 17.1%, 15.4% and 11.8% of raw material purchases, two customers accounted for 47.4% and 14.0% of accounts receivable, and three different products accounted for 41%, 17% and 16% of revenue.

NOTE 14 – SUBSEQUENT EVENTS

In accordance with ASC 855-10 the Management reviewed the Company's operations subsequent to December 31, 2018 to the date these consolidated financial statements were issued, and has determined the Company does not have any material subsequent events to disclose in these consolidated financial statements.