

CHINA PHARMA HOLDINGS, INC.  
Form 10-K  
April 02, 2018

**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, 2017**

**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 (IRS Employer  
incorporation or organization) 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:

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.001 Par Value Per Share	NYSE MKT

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

Do not check if a 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: \$10,45,054 as of June 30, 2016, based on the closing price of \$0.24 of the Company's common stock on such date.

The number of outstanding shares of the registrant's common stock on March 27, 2018, was 43,579,557.

Documents Incorporated by Reference: None.

**FORM 10-K ANNUAL REPORT**

**FISCAL YEAR ENDED DECEMBER 31, 2017**

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## **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, 2017, 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.

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 sterilize 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 with 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 from the National Bureau of Statistics of China, the pharmaceutical manufacturing industry's revenue and profit growth increased by more than 25% from 2009 to 2011, but began to decline year by year; and reached its lowest point in 2015. In 2016, it slightly recovered due to sustained growth at around 10% and 14%, respectively. From January to November 2017, the pharmaceutical industry recorded income of RMB2.59 trillion (approximately USD0.40 trillion), or an increase of 12.3% compared to the same period in 2016, showing a more favorable trend. In general, the pharmaceutical industry was no longer in the rapid growth phase, but rather a relatively slower and internally differentiated growth phase.

From the perspective of industrial policy, the pharmaceutical industry has gone through two stages in the recent decade: (1) a golden period, as the industry developed rapidly before 2011 along with the expansion of China's medical insurance system; and (2) a period of decline, in which the growth rate has visibly deteriorated since 2012, partly due to the new rural cooperative medical system and urban residents' medical insurance system roughly reaching full coverage, thus, causing the growth rate of funding of China's medical insurance system to decline, and pricing pressure to be put into the spotlight.

Various reform policies have been promulgated and enforced since 2016. With the advancement of public hospital reforms and progression of the drug regulatory system, the diversity among manufacturers has further intensified. The key takeaways from 2017 include the implementation of policy: a drug bidding process was approved in various provinces, the two-invoice system was fully launched, the new medical insurance catalog was launched, the drug supervision system was further promoted, and implementation explanations around consistency evaluation were issued. It is likely that the environment of the pharmaceutical industry will be refined, and the development of the industry will enter a new era.

Although 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 fiscal expenditures in healthcare are expected to continue to increase. Therefore, we believe that demand for pharmaceuticals and consumer ability to pay is still enjoying steady growth. Although the growth rate has been declined, our industry is now very large-scale.

### *Consistency Evaluation*

The development of generic drugs is an important measure to reduce medical expenses. By conducting generic drug consistency evaluation, 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.

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, 17740 production approval numbers, 1817 domestic pharmaceutical manufacturers, and 42 overseas manufacturers will be affected by the Opinions. Unfortunately, annual sales of most of those 17740 production approval numbers did not exceed RMB5 million. In which case, manufacturers make wait and extended period of time to recoup the capital investment for consistency evaluation. The similarities in the pharmaceutical market in China lead to low profit rate. The money invested in consistency evaluation comes from the manufacturer; therefore in general, manufacturers prefer to take consistency evaluation of selected existing products with higher profitability.



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 evaluation, 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 the payment of medical 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 evaluation is 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. According to data from China National Health Information Corporation, in 2016, the total scale of China's pharmaceutical end-use market (without medicinal materials) amounted to RMB1.49 trillion (approximately USD 0.23 trillion). It is said that the consistency assessment and the revision of the national drug standards will involve the reshuffle of the RMB1 trillion (approximately USD 0.15 trillion) market.

Bioequivalence testing (BE Testing) is an important component of Consistency Evaluations. Unfortunately, there are a limited number of institutions that currently carry out BE Testing, which has become for a significant brake on the progress of the Consistency Evaluation program. The PRC had more than 400 clinical drug trial institutions back in 2016, while, per the "Notice on the Clinical Trial Practice by Clinical Trial Institutions and Contract Research organizations" issued by CFDA on September 9, 2015, there were only 82 clinical drug trial institutions that had undertaken BE Testing and Phase I clinical trial. Fortunately, the government has aggressively addressed this problem in recent years. CFDA issued the "Certification of Pharmaceutical Clinical Trial Qualifications (No. 9) (No. 165 of 2017)" on December 28, 2017. Together with the 618 clinical drug trial institutions previously released, so far the number of clinical drug trial institutions has reached 625.

BE 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 injections.

### *The PRC’s medical insurance system*

The PRC started putting basic medical insurance in place for urban workers in 1998, kicked off the “New Rural Cooperative Program” (new rural cooperative medical care program) in 2003, and implemented basic medical insurance for urban residents in 2007 to cover unemployed and low-income urban residents. After 20 years of hard work, basic medical insurance has almost covered the entire population. The universal health insurance, consists mainly of basic medical insurance for employees, basic medical insurance for urban residents, and new rural cooperative medical care. By the end of 2016, there were more than 1.3 billion people participating in the basic medical insurance system in China, and the coverage rate of the insurance coverage was more than 95%. In 2016, the state officially initiated the integration of the two systems of urban residents’ basic medical insurance and new rural cooperative medical care. From January to November 2017, the number of urban basic medical insurance participants was RMB1.15 billion (approximately USD0.18 billion), an increase of 63.7% year-on-year, and the amount of funds raised was RMB1.58 trillion (approximately USD0.24 billion), an increase of 40.6% year-on-year, and expenditure was RMB1.23 trillion (approximately USD0.19 billion), an increase of 35.7% year-on-year. The increase in the number of insured persons, the growth of fundraising and the acceleration of expenditures were mainly due to the accelerated progress of the integration of the two programs.



The reimbursement rates for outpatient and inpatient expenses for new rural cooperative medical care remained stable at around 50% and 70%, respectively in 2017. The Ministry of Human Resources and Social Sciences issued the 2017 edition of Medical Insurance Drug List (MIDL 2017) on February 23, 2017. The MIDL 2017 included 2,535 drugs, which represented an increase of 339 drugs, or 15.4% compared to 2009 edition; among which included 1297 western drugs, which represented an increase of 133 drugs, or 11.4%; and 1238 traditional Chinese medicine, which represented an increase of 251 or 25.4%. The MIDL 2017 reflected the government's policy on "filling vacancies, selecting the best, supporting innovation, encouraging competition"; and gave special consideration and support for children's medicines, innovative medicines, major disease treatment medicines and ethnic medicines.

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 need and high degree 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.

At the end of 2017, medical insurance payment reforms were accelerated throughout the country, and multiple compound medical insurance payment methods based on disease-based payment were gradually introduced. According to a rough estimate, nearly two-thirds of the country's provinces have implemented or are piloting the implementation of a disease-based charge.

There are other factors that may also affect the pharmaceutical industry, such as Medicare cost-controls. In order to control the rapid increase in medical expenditures, the government of the PRC has, since 2010, introduced a series of policies to strengthen supervision and control effects of Medicare on healthcare services, to reform the Medicare payment methods, to establish a hierarchical treatment system, to eliminate pharmaceutical mark-ups, and to reduce the proportion of drug costs to total healthcare costs, etc. In June 2016, the PRC's National Health Commission called on each province to determine the growth rate of medical expenditures as soon as possible and further proposed limiting the national medical expenditure growth rate to no higher than 10% by the end of 2017. The General Office of the State Council issued the "Guiding Opinions on Further Deepening the Reform of Basic Medical Insurance Payment Methods." on June 28, 2017. The goal is to further strengthen the budget management of the Medicare fund from 2017 onwards, and fully implement multiple compound medical insurance payment methods based on disease-based payment. We believe that Medicare cost-controls have been a consistent theme of our industry. These cost-controls have been a serious challenge for medical institutions, manufacturing companies, and drug-logistic companies.

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 basic principles and standards for the manufacturing of pharmaceutical products and the management of quality controls in pharmaceutical manufacturing processes in the PRC. Since they were first adopted in 1988, GMP have over two decades of history in China, and were revised in 1992 and 1998. As of June 30, 2004, all manufacturing of active pharmaceutical ingredients (“API”) and finished dosages must be in compliance with the GMP standards. The new GMP standards that became effective on March 1, 2011, include improvements based upon foreign manufacturing advancements, and have taken into consideration local conditions in China. Based on the principle of “equal importance between hardware and software”, strictly implementing the idea of risk control during the manufacturing process of pharmaceutical products, and increased focus on scientific guidance and operability, the new GMP standards are consistent with the World Health Organization (WHO) standards.

The four main prongs of the new GMP standards are: (1) strengthening quality control systems during the manufacturing process of pharmaceutical products by significantly increasing requirements regarding quality control software; (2) improving requirements regarding the quality of practitioners; (3) refining operational procedures, rules on document management (including manufacturing records), improving guidance and operability; and (4) further improvements related to measures to ensure the safety of pharmaceutical products.

The Drug Marketing Authorization Holder (“MAH”) model is a management model that separates marketing authorization from independent production licensing. License holders may delegate production to manufacturers and are only responsible for the safety, effectiveness and quality control of drugs manufactured for public consumption. The MAH model is a common worldwide practice for review and approval of new drugs, and h encourages investment in research and development and the adoption of Contract Manufacturing Organization.

In August 2015, the PRC State Council issued “Opinions on the Reform of Drug and Medical Devices Evaluation and Approval of System Review”, which proposed to implement the MAH system experiments. Because the Company is considered a manufacturer pursuant to this policy, we believe this policy will benefit our Company in the long run, given our new GMP certified production facility and because we have the potential to manufacture products for license holders in the future.

## **Our Strategy**

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. According to the *2017 National Economic and Social Development Statistics Bulletin of the People’s Republic of China* issued by National Bureau of Statistics of the PRC, the total number of Chinese healthcare institutions has reached 995,000 as of the end of 2017, including 30,000 hospitals, 940,000 grass-root healthcare institutes (comprised of 37,000 township healthcare centers, 35,000 community health service centers (stations), 230,000 clinics, 638,000 village healthcare centers), and 22,000 professional public health institutions. We believe the increase in demand from these sources should allow us to grow organically. In addition, the total number of medical personnel in the PRC has reached 8.91 million, including 3.35 million practicing physicians and practicing assistant physicians and 3.79 million registered nurses. The number of beds in medical and health institutions has reached 7.85 million, including 6.09 million in hospitals and 1.25 million in township healthcare centers.

Production approval from the CFDA for Candesartan, an angiotensin II receptor antagonist serving as a first-line treatment for hypertension, developed in November 2013 and launched towards the end of 2014, and for new products from our pipeline of products under development (such as a generic version of Crestor and novel anti-drug-resistant combination antibiotics), would offer us significant growth opportunities. Finally, healthcare reform has started to change the landscape of the Chinese pharmaceutical industry, which we believe will create many attractive acquisition opportunities. We plan to explore these opportunities in an effort to add synergistic products that can help us grow our business.

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.

<b>Product</b>	<b>Indication</b>	<b>Year of Commercial Launch</b>
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	Cerebral thrombosis, coronary heart disease and complications after surgery such as thrombus deep phlebitis.	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	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.	1995
Cefaclor Dispersible Tablets	Tympanitis, lower respiratory tract infection, urinary tract infections and skin/skin tissue infection.	2002
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
Anhydroandrographolide	Ischemic heart disease, cerebrovascular diseases (cerebral thrombosis, cerebral embolism and coronary heart disease) and high lipoprotein blood disease.	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 Pseudoephedrine Hydrochloride 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
Omeprazole	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

The following table sets forth the aggregate amount and percentage of our revenues attributed to our product portfolio by indication group for the years ended December 31, 2017 and 2016.

Product Category	Year Ended December 31,		Net Change	%	
	2017	2016		Change	
CNS Cerebral & Cardio Vascular	2.07	2.72	-0.65	-24	%
Anti-Viro/ Infection & Respiratory	8.05	10.27	-2.22	-22	%
Digestive Diseases	0.69	0.79	-0.10	-13	%
Other	2.40	1.78	0.62	35	%

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*

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, including the Chinese Academy of Sciences, China University of Pharmaceuticals, Sichuan University, Chongqing Medical Industry Institute and the Military Medical Academy Basic Medical Science Institute. 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 obtained certificates and approvals of drug production for our Naproxen Sodium and Pseudophedrine Hydrochlorida sustained-release tablets through our cooperative relationship with the Chongqing Medical Industry Institute, and we also obtained certificates and approvals of drug production for our Cefalcor dispersible tablets through our cooperative relationship with the China University of Pharmaceuticals. We are now manufacturing and selling both drugs. We expect to continue to develop additional new drugs using this method. 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. We commenced leading formulation screening, a new technology exploration and technical criteria improvement activity, in 2013. We expect this new model to accelerate our development timelines and expand exploration channels for our pipeline products.

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 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 the “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. In addition, all oral solution generic drugs listed in National Essential Drugs List (2012 edition) and launched into the market before October 1, 2007, must undergo Consistency Evaluations by the end of 2018, and Consistency Evaluation should be completed by the end of 2021 for drugs with existing special conditions or those which require clinical efficacy trials. 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 our pipeline products in 2016. The following list sets forth the current status of our main pipeline products:

<b>Indication of Product Candidate</b>	<b>CFDA Status</b>
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 New Policy
Alzheimer's Disease drug	At the latest stage of supplementing Consistency Evaluation per the New Policy
Coronary Heart Disease Drug	Phase III Clinical Study Completed, and are supplementing clinical trials pursuant to the updated criteria

We have several other pipeline products in various stages of development.

### ***Distribution and Customers***

We believe we have a well-established sales network. As our current pharmaceutical product portfolio is comprised mainly prescription drugs, our major sales targets are hospitals. As of December 31, 2017, 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 as our operating subsidiary, Helpson, 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 GMP certificates for different forms including: tablets, capsule, dry power, liquid injectables, solid oral solution Cephalosporins (specifically designated).

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, 2017, our purchases from four suppliers accounted for 19.8%, 17.1%, 15.4% and 11.8% of raw material purchases. For the year ended December 31, 2016, our purchases from one supplier accounted for approximately 21.1% 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.

*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 address 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.

As of December 31, 2017, 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. This process generally takes two to five years and could be longer, depending on the nature of the medicine under review, the quality of the data provided and the workload of the CFDA. If 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.

*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.

### ***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.

*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.

The Ministry of Human Resources and Social Security announced the results of the Negotiations on the Catalogue of Medicare Drugs on July 9, 2017: 36 drugs have been successfully added to the Medicare Drug List, among which a variety of tumor-targeting drugs are listed, as well as drugs for treating major diseases such as cardiovascular diseases and hemophilia. Compared with the average retail price in 2016, the average price drop in negotiated drugs reached 44%, with the highest drop of 70%. In April this year, the Ministry of Human Resources and Social Sciences announced a list of 44 drugs to be negotiated. After negotiating with related companies, 36 drugs were successfully negotiated and were subsequently included in the “National Basic Medical Insurance, Industrial Injury Insurance and Maternity Insurance Drug Catalog (2017 Edition)” category B drugs.

In January 2017, the State Council issued the “13th Five-Year Plan for Deepening the Reform of the Medical and Health Care System”, and called for all levels of public hospitals to implement comprehensive reforms in 2017, and to abolish the practice of mark-ups on medicine (with the exception of Chinese herbs).

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. In 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%.

***Reimbursement under the National Medical Insurance Program***

According to the “Notice of Doing a Basic Health Insurance Work for Urban Residents in 2017” issued by the Ministry of Social Affairs of the People’s Republic of China in 2017: to raise the financial subsidy standard. Namely the per capita subsidy standard for resident medical insurance at all levels of finance will increase by RMB30 (approximately USD 5) on the basis of 2016, with an average of RMB450 (approximately USD 69) per person per year. Among them, the central government subsidizes the western and central regions in proportions of 80% and 60% respectively, and grants subsidies to each province in the eastern region according to a certain percentage. In 2017, the per capita personal payment standards for medical insurance for urban and rural residents will increase by RMB30 (approximately USD 5) on the basis of 2016, with an average of RMB180 (approximately USD 28) per person per year.

In the urban residents’ medical insurance policy in 2017, the proportion of compensation for inpatient medical expenses will be about 75%, and the proportion of basic medical institutions paying for general outpatient visits shall not be less than 50%. The proportion of reimbursement from different levels of medical institutions has been initiated, and the medical insurance payment policy has been favors the grass-roots level to facilitate full use of basic medical and health resources and promote the formation of hierarchical diagnosis and treatment.

Although it is designated as a national program, the implementation of the NMIP is delegated to various provincial governments, each of which has established its own medicine catalog. A provincial government must include all Tier 1 medicines listed in the national medicine catalog in its provincial medicine catalog, but may use its discretion based on its own selection criteria to add other medicines to, or exclude Tier 2 medicines listed in the national medicine catalog from its provincial medicine catalog, so long as the combined numbers of the medicines added and excluded do not exceed 15% of the number of the Tier 2 medicines listed in the national catalog. In addition, provincial governments may use their discretion to upgrade a nationally classified Tier 2 medicine to Tier 1 in their provincial medicine catalogs, but may not downgrade a nationally classified Tier 1 medicine to Tier 2.

The total amount of reimbursement for the cost of prescription and OTC medicines, in addition to other medical expenses, for an individual program participant in a calendar year is capped at the amount in that participant’s individual account. The amount in a participant’s account varies, depending upon the amount of contributions from the participant and his or her employer. Generally, on average, program participants who are from relatively wealthier eastern parts of China and relatively wealthier metropolitan centers have greater amounts in their individual accounts than those from less developed provinces.

Currently, 18 of our pharmaceutical products are listed on the National Insurance Catalogue (NIC), and three of our products - Cefalexin, Clarithromycin and Omeprazole - are listed on the Essential Drug List (EDL). However, some of our non-EDL drugs have been selected to enter the provincial EDL, which varies from province to province. We believe these drugs will experience an increase in sales volume due to the government-initiated promotion of those drugs, while remaining free from the pricing pressures often experienced by drugs listed on the EDL.

### ***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, 2017, we had 296 employees, among which 276 employees were full-time employees and 20 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 among 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:

perceptions by physicians, patients and others in the medical community about 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.

If we are not able to satisfy the requirements of the new GMP guidelines and obtain clearance from the CFDA, our existing dry powder injectable and granule production lines may be suspended and we may be subject to fines or other penalties if we continue to produce any products from such lines, all of which may have a material and adverse impact on our business, financial condition and results of operations.

***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.***

During our course of 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 should 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.

Recalls could 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. 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 18.7% for the year ended December 31, 2017, compared to gross profit margins of 20.7% for the year ended December 31, 2016. 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 substituted by 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 high level of governmental price control, 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 EDL.

***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 for which our products may be indicated. 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 may decline or we may be required to lower the price 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 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.

***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 period expires, 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. The interest of a hospital in a 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 making and keeping hospitals and physicians 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 affected by many factors. Products that appear to be promising at their early phases of research and development may fail to be commercialized for various reasons, including the failure to obtain the necessary regulatory approvals. In addition, the research and development cycle 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 trial and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial production and sales of these products. There is no assurance that our future research and development projects will be successful or completed within the anticipated time frame or budget or that we will receive the necessary approvals from relevant authorities for the production of these newly developed products, or that these newly-developed products will achieve commercial success.



Others may obtain approval for a competitive product before the product we are developing is approved. In that case, we may be precluded from getting approval until the competitor's monitoring period expires and realize little or 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. In addition, the pharmaceutical industry is characterized by rapid changes in technology, constant enhancement of industrial know-how and 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 improving our existing products or developing new products in a timely manner or these products do not achieve 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 research and development of new products. We 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. In addition, 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 or prevent or limit 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.

***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 upon advantageous 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, 2017, no customer accounted for more than 10.0% of sales, and one customer accounted for 47.4% 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 and our financial results could be adversely affected if we cannot find the equivalent 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 and 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 14% and 21% of our net revenues in 2017 and 2016, 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 could expose us to the risk of substantial losses if a single large distributor stops purchasing our products, purchases fewer 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 the drugs with the same active ingredient, dosage form, delivery channel and therapeutic effects compared to the original drugs. “Consistency Evaluation” requires currently marketed generic products to prove consistency in term of quality and therapeutic effect, and substitutable 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 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 its CFDA approval due to this additional new requirement and the Company strives 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 requirement, 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, 2017, four suppliers accounted for 19.8%, 17.1%, 15.4% and 11.8% of raw material purchases and the year ended December 31, 2016, purchases from one supplier accounted for 21.0% of 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 relationship 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, both of 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.

In addition, 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 the 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 marketing 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 what types of payments to promote or sell our products 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 are considered by us or them 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



to date no material claim for personal injury resulting from allegedly defective products has been brought against us, 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. 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 determine to devote significant amount of financial resources to the development of products that we believe to have significant commercialization potential;

we determine 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 to be not 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 determine 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, 2017, we had 296 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 the services of Ms. Li 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. We may not at all times comply fully with environmental regulations. Any violation of these regulations may 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. 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 deduction 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 2017 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 from a third party for a pharmaceutical compound 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 assurance that there will not be any infringement of our brand name or other registered trademarks or counterfeiting of our products in the future. There is no assurance that there will not be any third-party infringement of our patent. 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.

***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 from 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 wholly foreign-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.

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 assurances 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 can be no assurance 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. In addition, 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 and 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.

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 the renewal of the waste disposal permit. There is no assurance that we will obtain the 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 can be no assurance 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 share 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 a securities offering 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 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;

additions or departures 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, 2017, and there existed a material weakness in our internal control over financial reporting as of December 31, 2017.

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 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 their 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 a line of credit with Bank of China in October 2013, which was renewed in November 2014 and November 2015. This line of credit was payable in two equal installments of RMB 15,000,000 (\$2.25 million) payable on September 22, 2016 and October 20, 2016. In order to secure the line of credit, Helpson mortgaged its land use rights and buildings. To provide an additional security, our Chief Executive Officer and Chairman of our Board of Directors personally guaranteed the new line of credit. This line of credit has been fully paid off and the associated mortgage was lifted.

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 RMB20 million (approximately \$3.1 million) of the construction loan per the payback schedule as of December 31, 2017. 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:

<b>Total Amount of the Line of Credit</b>	<b>Lending Institution</b>	<b>Contract Period</b>	<b>Interest Rate</b>	<b>Properties under Mortgage</b>
RMB 80 million (Approximately \$12.3million)	Bank of China	July 11, 2013 to July 10, 2021	The interest rate is 5.73%, 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, 2015, the interest rate was adjusted to 5.94%.	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 MKT (Formerly known as NYSE Amex) 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.”

The following table, based upon historical data from Yahoo Finance, contains information about the range of high and low sales prices for our common stock for each full quarterly period during the fiscal years ending December 31, 2017 and 2016.

	High	Low
Fiscal 2017		
First Quarter	\$0.33	\$0.21
Second Quarter	0.33	0.15
Third Quarter	0.25	0.16
Fourth Quarter	0.25	0.15
Fiscal 2016		
First Quarter	\$0.21	\$0.12
Second Quarter	0.30	0.17
Third Quarter	0.32	0.21
Fourth Quarter	0.29	0.17

## Holders

As of March 27, 2018, there were approximately 137 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

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

## **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**

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 object of evaluations and establish deadlines,



determine selection criteria for reference drugs, call for a rational selection of evaluation methods, and 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 has assessed each pipeline product based on the adjusted CFDA approval criteria and clinical trial requirements, as well as the estimated additional investment for consistency evaluation, and potential return of investment once launched into the market; and decided to terminate the progress of certain pipeline products. Performing consistency evaluations will become our core task in the near future in order to have our pipeline products receive the final registration approval, therefore, it will have a significant impact on 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 some key products in 2017.

Increasing our sales remains our top priority. Through the continued implementation of sales promotion, the Company realized sales increases in the fourth quarter of 2017 compared to the previous quarter. Management will continue to vigorously promote sales by actively participating in the recent opening of the new provincial drug tender and participation in drug exhibitions.

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, Management has suspended the development of our pipeline products in 2017. 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 are supplementing consistency evaluation experiments pursuant to the Opinions.

## **Market Trends**

Consumer demand for medicine is relatively rigid and stable and is generally unaffected by seasonal business cycles. We have noticed that the growth rates of the pharmaceutical manufacturing industry have 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 to reduce 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, especially in compliance with consistency evaluations, we could meet European and American production standards, enabling us to export products to overseas markets



In August 2015, the State Council promulgated the “*Opinions on the Reform and Examination of the Approval System for the Reform of Drugs and Medical Devices*”, which was the prelude to the reform of the drug examination and approval system, the reform 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, and 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 the “*Pilot Plan for Marketing Authorization Holders*” on May 24, 2016, allowing eligible drug research and development institutions and scientific researcher 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 a 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, 2017**

### ***Revenue***

Revenue decreased by 15.2% to \$13.2 million for the year ended December 31, 2017, as compared to \$15.6 million for the year ended December 31, 2016. This decrease was mainly due to the negative impact around Health-care insurance cost-control as well as policies for reducing the proportion of drug cost to total health-care spending.



Set forth below are our revenues by product category in millions (USD) for the years ended December 31, 2017 and 2016:

Product Category	Year Ended December 31,		Net Change	% Change	
	2017	2016			
CNS Cerebral & Cardio Vascular	2.07	2.72	-0.65	-24	%
Anti-Viro/ Infection & Respiratory	8.05	10.27	-2.22	-22	%
Digestive Diseases	0.69	0.79	-0.10	-13	%
Other	2.40	1.78	0.62	35	%

The most significant revenue decrease in terms of dollar amount was in our Anti-Viral/Infection & Respiratory” product category, which generated \$8.1 million in sales revenue in 2017 compared to \$10.3 million a year ago, a decrease of \$2.2 million. This decrease was mainly due to the sales decrease of our Cefaclor Dispersible Tablets in this category, which was a result of drug pricing control policies, as well as market fluctuation.

Sales in the “CNS Cerebral & Cardio Vascular” category decreased by \$0.7 million to \$2.1 million in 2017 compared to \$2.7 million in 2016, which decrease was mainly due to a drop in sales of Ozagrel, primarily the result of volatility in market demand. Our “Digestive Diseases” category generated \$0.7 million of sales in 2017, compared to \$0.8 million in 2016. Our “Other” product category sales increased by \$0.6 million to \$2.4 million in 2017 from \$1.8 million in 2016, mainly due to the increase in sales of Vitamin B6, caused by market volatility.

Product Category	Year Ended December 31,	
	2017	2016
CNS Cerebral & Cardio Vascular	16 %	18 %
Anti-Viral/ Infection & Respiratory	61 %	65 %
Digestive Diseases	5 %	5 %
Other	18 %	12 %

For the year ended December 31, 2017, revenue breakdown by product category remained close to that of the prior year. Sales of the “Anti-Viral/Infection & Respiratory” products category represented 61% and 65% of total sales in the years ended December 31, 2017 and 2016, respectively. The “CNS Cerebral & Cardio Vascular” category represented 16% of total revenue in 2017, compared to 18% in 2016. The “Digestive Diseases” category represented 5% of total revenue in both 2017 and 2016. The “Other” category represented 18% and 12% of revenues in 2017 and 2016,

respectively.

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### ***Cost of Revenue***

For the year ended December 31, 2017, our cost of revenue was \$10.7 million, or 81.3% of total revenue, which represented a decrease of \$1.6 million from \$12.4 million, or 79.3% of total revenue, in 2016.

### ***Gross Profit and Gross Margin***

Gross profit for the year ended December 31, 2017 was \$2.5 million, compared to \$3.2 million in 2016. Our gross profit margin in 2017 was 18.7% compared to 20.7% in 2016. This decline in our gross profit margin was mainly due to that our raw material prices have generally risen in recent quarters along with the improvement of industry standards and the strengthening of environmental protection requirements. In addition, adverse drug pricing control policies have negatively impacted our gross margins.

### ***Selling Expenses***

Our selling expenses for the year ended December 31, 2017 were \$3.5 million, a decrease of \$0.6 million compared to \$4.0 million for the year ended December 31, 2016. Selling expenses accounted for 26.2% of the total revenue in 2017 compared to 25.9% in 2016. The increase was mainly the result of additional marketing, consulting and product promotional efforts in certain Chinese provinces. Because of adjustments in our sales practices resulting from healthcare reform policies, despite the overall decrease in sales, we require additional personnel and expenses to support our sales and the collection of accounts receivable.

### ***General and Administrative Expenses***

Our general and administrative expenses for the year ended December 31, 2017 were \$2.0 million, which represented a decrease of \$0.2 million compared to \$2.3 million in 2016. General and administrative expenses accounted for 15.3% and 14.6% of our total revenues in 2017 and 2016, respectively.

### ***Research and Development Expenses***

Our research and development expenses for the year ended December 31, 2017 were \$0.1 million, compared to \$0.4 million in 2016. Research and development expenses accounted for 0.7% and 2.4% of our total revenues in 2017 and 2016, 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 did not have any further development in 2017.

***Bad Debt Expenses***

Our bad debt expenses for the year ended December 31, 2017 was \$1.4 million, which represented an increase of \$0.3 million compared to \$1.1 million in 2016. The increase in our bad debt expenses was mainly due to the change in the composition of aging of accounts receivables for the year ended December 31, 2017 compared to December 31, 2016.

In general, our normal customer credit or payment terms are for 90 days. This has not changed in recent years. 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 90 days old) was \$1.6 million and \$3.9 million as of December 31, 2017 and 2016, respectively.

The following table illustrates our accounts receivable aging distribution in terms of percentage of total accounts receivable as of December 31, 2017 and 2016:

	December 31, 2017		December 31, 2016	
1 - 90 Days	3.9	%	8.8	%
90 - 180 Days	1.6	%	2.6	%
180 - 360 Days	2.4	%	6.7	%
360 - 720 Days	13.6	%	13.4	%
> 720 Days	78.5	%	68.5	%
Total	100.0	%	100.0	%

Our bad debt allowance estimate is currently 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 benefit for the difference. The allowance for doubtful accounts was \$18.2 million and \$15.7 million as of December 31, 2017 and December 31, 2016, respectively. The changes in the allowances for doubtful accounts during the years ended December 31, 2017 and 2016 were as follows:

	For the Fiscal Years Ended	
	December 31,	
	2017	2016
Balance, Beginning of Period	\$ 15,664,496	\$ 29,352,806
Bad debt expense	1,393,576	1,086,449
Charged to reserve	-	-13,519,167
Foreign currency translation adjustment	1,151,662	-1,255,592
Balance, End of Period	\$ 18,209,734	\$ 15,664,496

### ***Impairment of Intangible Assets***

Our impairments for the year ended December 31, 2017 were \$13.6 million, compared to \$4.0 million in 2016. 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, 2017 and December 31, 2016 respectively, and identified six and five 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, 2017 was \$18.7 million, compared to an operating loss of \$8.2 million in 2016.

### ***Net Interest Expense***

Net interest expense for the year ended December 31, 2017 was \$0.5 million, compared to \$0.7 million in 2016. 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 9 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, 2017, and 15% for the year ended December 31, 2016. Our income tax expense was (\$0.1) million and (\$0.3) million for year ended December 31, 2017 and 2016, 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 for Helpson for 2017 and the foreseeable future will be 25%.

### ***Net Loss***

Net Loss for year ended December 31, 2017 was \$19.3 million, compared to net loss of \$9.2 million for the year ended December 31, 2016. The increase in net loss was mainly a result of the increase in impairment loss and bad debt expenses.

For the year ended December 31, 2017, loss per basic and diluted common share was \$0.44, compared to loss per basic and diluted share of \$0.21 for the year ended December 31, 2016.

The number of basic and diluted weighted-average outstanding shares used to calculate loss per share was 43,579,557 for both 2017 and 2016.

### **Liquidity and Capital Resources**

Our principal sources of liquidity are cash generated from operations. Our cash and cash equivalents were \$2.0 million, representing 3.4% of our total assets as of December 31, 2017, as compared to \$2.7 million, representing 3.4% of our total assets as of December 31, 2016. All of the \$2.0 million of cash and cash equivalents as of December 31, 2017, 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 \$13 million), which had been fully utilized through May 7, 2014. We’ve incrementally repaid the principle of RMB 21 million (approximately \$3.2 million) of the construction loans per the payback schedule as of

December 31, 2017. The current portion of the construction loan facility is \$2.3 million as of December 31, 2017. The cash flow generated from operating activities was used to fund our daily operating expenses as well as 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 and the remaining new GMP upgrade related construction and equipment in our existing facility 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. 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 \$0.8 million in the year ended December 31, 2017, compared to \$2.9 million for 2016.

As of December 31, 2017, our accounts receivable was \$2.3 million, a decrease of \$1.7 million from \$4.0 million as of December 31, 2016. The decrease was mainly due to \$1.4 million of bad debt expenses recognized in 2017.

As of December 31, 2017, total inventory was \$6.4 million, a decrease of \$0.9 million from \$7.3 million as of December 31, 2016. This decrease was mainly due to we improved the management of inventory turn-over in 2017.

### ***Investing Activities***

During the year ended December 31, 2017, net cash used in investing activities was \$0.1 million, compared to \$0.2 million for the year ended December 31, 2016.

### ***Financing Activities***

Cash flow used in financing activities was \$1.5 million in the year ended December 31, 2017; compared to \$6.0 million in the year ended December 31, 2016. In 2017, the decrease in cash flow used in financing activities was mainly due to the repayment of the RMB 30,000,000 (approximately \$4.5 million) line of credit facility in 2016.



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, 2017 and 2016, the net assets of Helpson were \$40,034,000 and \$55,062,000, respectively. Due to the restriction on dividend distribution to overseas shareholders, the amount of Helpson's net assets that were designated for general and statutory capital reserves, and thus could not be transferred to our parent company as cash dividends, were \$8,145,000 and \$8,145,000 (50% of registered capital) for the fiscal years ended December 31, 2017 and 2016, respectively. Since the amount that Helpson must set aside for the statutory surplus fund only accounts for 20.3% and 14.8%, 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, 2017.

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 the ability of Helpson, our Chinese subsidiary, to transfer its net assets to our parent company through loans, advances or cash dividends.

### **Off-Balance Sheet Arrangements**

As of December 31, 2017, we did not have any off-balance sheet arrangements.

## **Commitments**

As of December 31, 2017, we were obligated to pay laboratories and other service providers approximately \$1.1 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, 2017 and 2016, 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, 2017 and 2016, 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, 2017. Based on that evaluation, our Chief Executive Officer and interim Chief Financial Officer concluded that as of December 31, 2017, 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, 2017. 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, 2017, 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, 2017, 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 27, 2018, along with their positions, offices and term:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Zhilin Li	65	Chairman, President, Chief Executive Officer and interim Chief Financial Officer
Heung Mei Tsui	61	Director
Gene Michael Bennett	70	Independent Director
Yingwen Zhang	73	Independent Director
Baowen Dong	77	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. Her role as one of the founders of our Company and her extensive experience in bio-engineering make her well suited to serve as our Chairman.

**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. Her experience in the trading side of the business affords her unique insights into the pharmaceutical industry, and her presence on our board of directors benefits the company greatly in the areas of strategic planning and execution.

**Gene Michael Bennett** has served as our independent director since February 2008. From July 2016 through the present, Mr. Bennett has served as CEO for Faroway Consulting in Shenzhen and CFO for 7 Senses Labs, both located in Shenzhen, Guangdong Province, China. Mr. Bennett also served as advisor to Swiss Capital Asia, located in Hong Kong since 2013. From 2009 through 2013, Mr. Bennett served as the CEO of the 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 acted as 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 the 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. Mr. Bennett's extensive background in accounting, financial management and reporting, including SEC related reporting qualifies him to serve as an independent director of our company and the chairman of our audit committee.

**Yingwen Zhang** has served as our independent director since February 2008. He also currently serves as the consultant of Shanghai Reseat Medical Tech Co. Ltd., a medical device producer, and a director and a member of the compensation committee of Chongqing Wanli Battery Holdings (Group) LLC (SHA:600847). He acted as Senior Consultant and Chairman of Safety Production 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 then became a senior manager for several chemical corporations in China. From 1983 to 1988, Mr. Zhang served as the Chief Executive Officer 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. Mr. Zhang's extensive knowledge in areas of government regulation and policies, his experience as director of a China listed company, as well as his vast experience in senior management in SOE and the private sector, qualify him as an independent director of our company.

**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. His strong academic background in science and research brings value to our company in respect of research and development and qualifies him to serve as a director of our company.

### **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, 2017, 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, 2017, 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](http://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](http://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, 2017.

**SUMMARY COMPENSATION TABLE**

Name and principal position	Year Ended	Salary (\$)	Bonus (\$)	Stock	Option	Non-Equity	Nonqualified	All Other Compensation (\$)	Total (\$)
				Awards (\$)	Awards (\$)	Incentive Plan Compensation (\$)	Deferred Compensation Earnings (\$)		
Zhilin Li Chairman, Chief Executive Officer, President and interim Chief Financial Officer	2017	225,600	-	-	-	-	-	16,000	241,600
	2016	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, 2020. Upon the expiration of the original agreement, Helpson renewed the agreement with Ms. Li on the same terms as the original agreement. 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, 2017, 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 27, 2018, 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, 2017.

### 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	6,433	-	-	-	-	-	6,511
Baowen Dong	6,433	-	-	-	-	-	6,511

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 19, 2017, 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 \$5,760), 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 \$0.20 per share. As of the date of this report, no warrants have been issued to Mr. Bennett.

On December 21, 2016, we renewed the engagement letters with each of our three independent directors. Pursuant to the renewed engagement letters on the same terms and conditions as the previous engagement for a term of one year, each of Mr. Zhang and Mr. Dong is entitled to receive annual compensation of RMB40,000 (approximately \$5,920), 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 \$0.18 per share.

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

The following table sets forth certain information as of March 27, 2018, 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 27, 2018, 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 27, 2018, 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 27, 2017, 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 27, 2018 (for those who have options or warrants).

Pursuant to the terms of his engagement letters, Mr. Bennett is entitled to receive warrants to purchase an aggregate (4) of 40,000 shares of our common stock (5,000 shares in each of year between 2008 to 2016 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, 2017 and 2016. 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, 2017 and 2016, respectively.

### **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 MKT.

## **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

### ***Audit Fees***

The aggregate fees billed by B F Borgers CPA PC, our current principal accountant, and ArshakDavtyan, Inc., our former 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 the fiscal year ended December 31, 2017, and \$166,000 for the fiscal year ended December 31, 2016.

### ***Audit-Related Fees***



We did not incur any audit-related fees during the fiscal years ended December 31, 2017 and 2016.

***Tax Fees***

We did not engage our current principal accountant or our former principal accountant to render tax services to us during the last two fiscal years.

***All Other Fees***

We did not engage our current principal accountant or our former 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, 2017.

**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 Firms are presented in the “F” pages of this report:

Report of B F Borgers CPA PC, Independent Registered Public Accounting Firm

Consolidated Balance Sheets - as of December 31, 2017 and 2016

Consolidated Statements of Operations and Comprehensive Loss - for the years ended December 31, 2017 and 2016

Consolidated Statements of Shareholders' Equity - for the years ended December 31, 2017 and 2016

Consolidated Statements of Cash Flows - for the years ended December 31, 2017 and 2016

Notes to Consolidated Financial Statements

(b) Exhibits

See the Exhibit Index following the signature page of this report, which Index 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: April 2, 2018 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)	April 2, 2018
/s/ Heung Mei Tsui Heung Mei Tsui	Director	April 2, 2018
/s/ Gene Michael Bennett Gene Michael Bennett	Director	April 2, 2018
/s/ Yingwen Zhang Yingwen Zhang	Director	April 2, 2018
/s/ Baowen Dong Baowen Dong	Director	April 2, 2018

**CHINA PHARMA HOLDINGS, INC.**

**Exhibit Index to Annual Report on Form 10-K**

**For the Fiscal Year Ended December 31, 2017**

**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 Engagement Letter dated December 9, 2015 by and between the Company and Ms. Heung Mei Tsui for Ms. Tsui serving as a director of the Company (incorporated by reference to Exhibit 10.1 to our Annual Report on Form 10-K filed on March 30, 2016).
- 10.2 Engagement Letter dated December 9, 2015 by and between the Company and Ms. Zhilin Li for Ms. Li serving as a director of the Company (incorporated by reference to Exhibit 10.2 to our Annual Report on Form 10-K filed on March 30, 2016)..
- 10.3 Form of Independent Director Engagement 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).
- 23.1\* Consent of B F Borgers CPA PC
- 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.**

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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, 2017 and 2016, 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, 2017 and 2016, 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

April 2, 2018

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**CHINA PHARMA HOLDINGS, INC.****CONSOLIDATED BALANCE SHEETS**

	December 31, 2017	December 31, 2016
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 2,030,214	\$ 2,665,802
Restricted cash	709,796	1,088,879
Banker's acceptances	39,867	-
Trade accounts receivable, less allowance for doubtful accounts of \$18,209,734 and \$15,664,496, respectively	\$ 2,293,120	\$ 3,999,809
Other receivables, less allowance for doubtful accounts of \$40,010 and \$71,548, respectively	\$ 162,981	\$ 224,373
Advances to suppliers	461,307	2,003,792
Inventory	6,407,155	7,310,939
Prepaid expenses	185,647	226,357
Total Current Assets	12,290,087	17,519,951
Advances for purchases of intangible assets	23,722,954	35,498,059
Property and equipment, net	23,541,003	24,967,448
Intangible assets, net	398,856	534,682
<b>TOTAL ASSETS</b>	<b>\$ 59,952,900</b>	<b>\$ 78,520,140</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Trade accounts payable	\$ 1,141,138	\$ 3,060,374
Accrued expenses	276,368	139,830
Other payables	2,858,701	2,502,694
Advances from customers	581,132	811,232
Other payables - related parties	1,354,567	1,354,567
Current portion of construction loan facility	2,305,430	1,440,154
Bankers' acceptance notes payable	709,796	1,088,879
Total Current Liabilities	9,227,132	10,397,730
Non-current Liabilities:		
Construction loan facility	6,916,291	8,640,927
Deferred tax liability	738,175	572,349
Total Liabilities	16,881,598	19,611,006
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, \$0.001 par value; 95,000,000 shares authorized; 43,579,557 shares and 43,579,557 shares outstanding, respectively	43,580	43,580
Additional paid-in capital	23,590,204	23,590,204

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Retained earnings	5,479,809	24,757,374
Accumulated other comprehensive income	13,957,709	10,517,976
Total Stockholders' Equity	43,071,302	58,909,134
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 59,952,900	\$ 78,520,140

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

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

	For the Year Ended	
	December 31,	
	2017	2016
Revenue	\$13,212,314	\$15,570,514
Cost of revenue	10,743,764	12,352,004
Gross profit	2,468,550	3,218,510
Operating expenses:		
Selling expenses	3,460,596	4,036,590
General and administrative expenses	2,019,949	2,265,851
Research and development expenses	90,474	365,969
Bad debt expense	1,393,576	1,086,449
Impairment loss	14,183,969	3,962,141
Total operating expenses	21,148,564	11,717,000
Subsidy income	-	343,023
Loss from operations	(18,680,014)	(8,155,467 )
Other income (expense):		
Interest income	64,414	130,575
Interest expense	(539,334 )	(849,557 )
Net other expense	(474,920 )	(718,982 )
Loss before income taxes	(19,154,934)	(8,874,449 )
Income tax expense	(122,631 )	(308,175 )
Net loss	(19,277,565)	(9,182,624 )
Other comprehensive income - foreign currency translation adjustment	3,439,733	(4,549,391 )
Comprehensive loss	\$(15,837,832)	\$(13,732,015)
Loss per share:		
Basic and diluted	\$(0.44 )	\$(0.21 )
Weighted average shares outstanding	43,579,557	43,579,557

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

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**CHINA PHARMA HOLDINGS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance, December 31, 2015	43,579,557	43,580	23,590,204	33,939,998	15,067,367	72,641,149
Net loss for the year				\$(9,182,624 )		(9,182,624 )
Foreign currency translation adjustment					\$(4,549,391 )	(4,549,391 )
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

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

**CHINA PHARMA HOLDINGS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Year Ended	
	December 31,	
	2017	2016
Cash Flows from Operating Activities:		
Net loss	\$(19,277,565)	\$(9,182,624)
Depreciation and amortization	3,291,330	3,078,074
Inventory write off	118,003	-
Bad debt expense	1,393,576	1,086,449
Deferred income taxes	122,631	308,175
Impairment loss	14,183,969	3,962,141
Changes in assets and liabilities:		
Trade accounts and other receivables	51,024	(1,097,556)
Advances to suppliers	1,614,958	380,779
Inventory	1,718,336	2,734,612
Trade accounts payable	(2,045,948 )	815,198
Accrued taxes payable	18,753	72,107
Other payables and accrued expenses	420,523	377,663
Advances from customers	(274,068 )	265,928
Prepaid expenses	(494,306 )	94,762
Net Cash Provided by Operating Activities	841,216	2,895,708
Cash Flows from Investing Activities:		
Purchases of property and equipment	(136,479 )	(193,404 )
Net Cash Used in Investing Activities	(136,479 )	(193,404 )
Cash Flows from Financing Activities:		
Payments of construction term loan	(1,479,944 )	(1,505,346)
Payments of short term notes payable	-	(4,516,039)
Net Cash Provided by Financing Activity	(1,479,944 )	(6,021,385)
Effect of Exchange Rate Changes on Cash	139,619	(263,877 )
Net (Decrease) Increase in Cash and Cash Equivalents	(635,588 )	(3,582,958)
Cash and Cash Equivalents at Beginning of Period	2,665,802	6,248,760
Cash and Cash Equivalents at End of Period	\$2,030,214	\$2,665,802
Supplemental Cash Flow Information:		
Cash paid for income taxes	\$-	\$-
Cash paid for interest	\$525,788	\$836,011
Supplemental Noncash Investing and Financing Activities:		
Issuance of banker's acceptances	\$709,796	\$1,088,879

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Accounts receivable collected with banker's acceptances	531,294	935,265
Inventory purchased with banker's acceptances	492,906	935,265

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

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**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

**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 and 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 the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the financial statements, and 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 purchased with maturities of three months or less.

**Restricted Cash** –Restricted cash includes cash that has been deposited with a bank to satisfy obligations outstanding under banker's acceptance notes issued by the Company as discussed in Note 8.

**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 \$1,393,576 and \$1,086,449 for the years ended December 31, 2017 and 2016, 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 and \$13.5 million against the allowance for the years ended December 31, 2017 and 2016, 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.

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**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

***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 expense in the period they are considered unlikely to be collected.

***Inventory*** – Inventory consists of raw materials, work in process and finished goods and are stated at the lower of cost or market. 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 predicible costs to completion and disposal, is lower than its cost, the specific inventory item is written down to its estimated net realizable value. Market for raw materials is based on replacement cost. Provisions for inventory write-downs are included in 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 for impairment annually 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. For the years ended December 31, 2017 and 2016 the Company evaluated its long-lived assets and determined that necessary impairment adjustments were \$14,183,969 and \$3,962,141, respectively. 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. For 2016, the impairment of \$3,962,141 was related to advances for intangible assets as discussed in Note 5.

***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 considered earned when the Company obtains persuasive evidence of an arrangement with the customer, when delivery of the products has occurred, when the sales price is fixed or determinable, and when collectability is reasonably assured. Delivery does not occur until products have been shipped to the customer, the risk of loss has transferred to the customer and customer acceptance has been obtained, customer acceptance provisions have lapsed, or the Company obtains objective evidence that the criteria specified in the customer acceptance provisions have been satisfied. The sales price is not considered to be fixed or determinable until all contingencies related to the sale have been resolved. Revenue is deferred when collectability is not considered to be reasonably assured.

**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.

**Retirement Benefit Plans** – The Company is required to make monthly contributions at prescribed rates to various employee retirement benefit plans organized by the provincial governments. The benefit plans of the government assume the retirement benefit obligations of all existing and future retired employees of the Company. The Company contributed \$244,153 and \$261,063 to retirement benefit plans for the years ended December 31, 2017 and 2016, respectively. Contributions to these plans are charged to expense as incurred.

**Advertising Costs** – Advertising costs are expensed when incurred. The Company did not incur any advertising costs for the years ended December 31, 2017 and 2016.

**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, 2017 and 2016, respectively.

**Credit Risk** – The carrying amount of accounts receivable included in the 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 new 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 viability of securing future debt instruments within the PRC.

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**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

*Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “*Revenue from Contracts with Customers*” (ASU 2014-09), which contains new accounting literature relating to how and when a company recognizes revenue. Under ASU 2014-09, a company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities.

The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. The Company has determined its method of transition and evaluated that this guidance will not have any impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, a new standard on accounting for leases. The ASU introduces a lessee model that brings most leases on 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 Accounting Standards Update 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 is currently evaluating the impact of the pending adoption of the new standard on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The standard addresses the classification and presentation of eight specific cash flow issues that currently result in diverse practices. This pronouncement is effective for annual reporting periods beginning after December 15, 2017. The amendments in this ASU should be applied using a retrospective approach. The Company has not completed an evaluation of the impact the pronouncement will have on its consolidated financial statements and related disclosures, but does not expect the impact to be material.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”). The ASU requires an entity to explain the changes in the total of cash, cash equivalents, restricted cash, and restricted cash equivalents on the statement of cash flows and to provide a reconciliation of the totals in that statement to the related captions in the balance sheet when the cash, cash equivalents, restricted cash, and restricted cash equivalents are presented in more than one line item on the balance sheet. This ASU is effective for annual and interim periods beginning after December 15, 2017, and is required to be adopted using a retrospective approach, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2016-18 may have on its consolidated financial statements.

From time to time, the FASB or other standards setting bodies issue new accounting pronouncements. Updates to the FASB ASCs are communicated through the 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.

**CHINA PHARM HOLDINGS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016****NOTE 2 – INVENTORY**

Inventory consisted of the following:

	December 31, 2017	December 31, 2016
Raw materials	\$ 4,733,679	\$ 5,962,271
Work in process	481,863	360,550
Finished goods	1,191,613	988,118
	\$ 6,407,155	\$ 7,310,939

**NOTE 3 - PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

	December 31, 2017	December 31, 2016
Permit of land use	\$432,910	\$405,645
Building	10,052,840	9,419,700
Plant, machinery and equipment	28,044,515	26,151,029
Motor vehicle	330,598	309,777
Office equipment	200,974	182,718
Total	39,061,837	36,468,869
Less: accumulated depreciation	(15,520,834 )	(11,501,421 )
Property and Equipment, net	\$ 23,541,003	\$ 24,967,448

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



<b>Asset</b>	<b>Life - years</b>
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, 2017 and 2016, depreciation expense was \$3,125,937 and \$2,815,167, respectively.

#### **NOTE 4 - INTANGIBLE ASSETS**

Intangible assets represent the cost of medical formulas approved for production by the CFDA. The Company did not obtain CFDA production approval for any medical formula during the year ended December 31, 2017 and 2016 and no costs were reclassified from advances to intangible assets in 2017 and 2016, respectively.

Approved medical formulas are amortized from the date CFDA approval is obtained over their individually identifiable estimated useful life, 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 \$165,394 and \$262,908 for the years ended December 31, 2017 and 2016, respectively, 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.

**CHINA PHARM HOLDINGS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

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

	December 31, 2017	December 31, 2016
Gross carrying amount	\$ 5,188,547	\$ 4,861,766
Accumulated amortization	(4,789,691 )	(4,327,084 )
Net carrying amount	\$ 398,856	\$ 534,682

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

Year	Amount
2018	117,257
2019	61,140
2020	37,793
2021	37,793
2022	37,793
Thereafter	107,080
Total	\$398,856

**NOTE 5 – ADVANCES FOR PURCHASES OF INTANGIBLE ASSETS**

In order to expand the number of medicines the Company manufactured and marketed, it has 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 is 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 end December 31, 2013. These patents have 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.

A typical CFDA approval process for the production of a generic medical product involves a number of steps that generally require three to five years to complete. If the medical formula is purchased at the point when the generic medical product receives the CFDA's approval for a clinical study, which is very typical for the Company, the clinical study that follows will usually take from one and a half to three years to complete. After completing the clinical study, the results are submitted to the CFDA and a production approval application is filed with the CFDA. In most cases, it will take between eight to eighteen months to prepare and submit the production approval application and obtain CFDA approval. Upon approving the generic medical product, the CFDA issues a production certificate and the Company can commence the production and sales of the generic medical product. As a result of this process, CFDA approval is expected to be received in approximately two to five years from the date the Company signs the medical formula contracts.

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.

As of December 31, 2017, the Company was obligated to pay laboratories and others approximately \$1.1 million upon the completion of various phases of contracts to obtain CFDA production approval of medical formulas.

During the year ended December 31, 2017, 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 four formulas to three of the independent laboratories were impaired. During the year ended December 31, 2016, with CFDA's tightened scrutiny procedure in connection with its review of production applications and based on the

Company's monitoring and assessment process, the Company determined six advanced payments to six 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, 2017 and 2016 in the amount of \$14,183,969 and \$3,962,141, respectively.

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**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

**NOTE 6 – RELATED PARTY TRANSACTIONS**

A member of the Company's board of directors (the "Board") had previously advanced the Company an aggregate amount of \$1,354,567 as of December 31, 2017 and 2016 which are 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 of \$13,546 was recognized for each of the years ended December 31, 2017 and 2016.

**NOTE 7 – NOTES PAYABLE**

In November 2014, the Company entered into a line of credit with a bank in the amount of RMB 30,000,000 (approximately \$4.5 million). Advances on the line of credit were due one year from the date of the advance and were collateralized by certain land use rights, buildings and accounts receivable and bear interest at an annual rate of 6.16% (based upon 110% of the PRC government's short term rate of 5.6% in November 2014). In addition, the Company's Chief Executive Officer and Chair of the Board personally guaranteed the line of credit. In November, 2015 the Company renewed its line of credit in the amount of RMB 30,000,000 (approximately \$4,498,169 with the same bank. The line of credit was fully paid in two equal installments of RMB 15,000,000 (approximately \$2.25 million) payable on September 16, 2016 and October 19, 2016, respectively.

**NOTE 8 – BANKER'S ACCEPTANCE NOTES PAYABLE**

In April 2016, 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 (the "Banker's 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 Notes issued to the third parties. The amount of these deposited balances is shown as "Restricted cash" on the accompanying balance sheets as of September 30, 2016. The maximum amount that the Company can issue under this agreement is limited to the lesser of RMB 30,000,000 (approximately \$4.5 million) or the amount of cash available to deposit against the Banker's Notes. In addition, the agreement calls for the payment of fees equal to 0.05% of the note amount to the bank. At December 31 2017 and 2016, the Company had outstanding Banker's Acceptance Notes in the amount of \$709,796 and \$1,088,879, respectively.

**NOTE 9 – CONSTRUCTION LOAN FACILITY**

The Company obtained a construction loan facility in the aggregate amount of RMB 80,000,000 (approximately \$13 million) from a construction loan facility dated June 21, 2013. The loan facility is for an eight-year term, which commenced on July 11, 2013, the initial draw-down date. The total loan facility is from the same bank that provided the line of credit as discussed in Note 7. 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, 2015, 2016 and 2017 the interest rate was adjusted to 5.94%, 5.39% and 5.73%, 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 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. For the years ended December 31, 2017 and 2016, the Company has made all required payments due under the loan. As of December 31, 2017, the Company had no additional amounts available to it under this facility.

Principal payments required for the next five years as of December 31, 2017 are as follows:

Year	Amount
2018	2,305,430
2019	2,305,430
2020	2,305,430
2021	2,305,431
	\$9,221,721

***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, 2017 approximated its fair value because the underlying instrument bears an interest rate that approximated current market rates.

**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

**NOTE 10 – SUBSIDY INCOME**

During the years ended December 31, 2017 and 2016, the Company received cash of \$0 and \$0.34 million related to a subsidy from the government for the technological innovation it has achieved and the industrial upgrading related to its new GMP certified facility. This has been recorded as “Subsidy income” in the accompanying Statement of Operations for the years ended December 31, 2017 and 2016, respectively.

**NOTE 11 - 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 on deferred tax assets and liabilities of a change in tax laws or rates 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 return 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, 2017, the Company has not identified any uncertain tax positions that it has taken. U.S. income tax returns for the years ended December 31, 2014 through December 31, 2017 and the Chinese income tax return for the year ended December 31, 2017 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 following enterprise income tax rates:

Year	Enterprise Income Tax Rate
2016	15%
2017	25%
2018	25%
Thereafter	25%

The provision for income taxes consisted of the following:

	Year Ended December 31,	
	2017	2016
Current	\$-	\$-
Deferred	122,631	308,175
Total income tax expense	\$122,631	\$308,175

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

	Years Ended December 31,	
	2017	2016
(Benefit) tax at statutory rate of 25%	\$(4,788,734)	\$(2,218,612)
Effect of tax holiday	-	837,089
Effect of change in tax rate from 15% to 25%	-	(8,094,456)
Other, primarily the difference in U.S. tax rates	8,077	7,903
Change in valuation allowance	4,903,288	9,776,251
Income tax expense	\$122,631	\$308,175



**CHINA PHARM HOLDINGS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

The effect of the tax holiday in 2016 amounted to a change in the tax expense of \$837,089, which was equivalent to basic and diluted earnings per share of (\$0.01) per share for the year ended December 31, 2016. The temporary differences which give rise to the deferred income tax assets and liability are as follows:

	December 31,	
	2017	2016
Deferred income tax assets:		
Allowance for doubtful trade receivables	\$4,552,432	\$3,916,124
Allowance for doubtful other receivables	10,002	17,959
Inventory obsolescence reserve	1,595,671	1,535,660
Expenses not deductible in current year	1,076,126	1,008,350
Advances for intangible assets impairment	4,387,237	793,624
PRC net operating loss carry forward	14,572,439	12,660,410
U.S. net operating loss carry forward	1,076,830	1,520,675
Total deferred income tax assets	27,270,737	21,452,802
Valuation allowance	(27,270,737)	(21,452,802)
Net deferred income tax asset	\$-	\$-
Deferred income tax liability:		
Intangible assets	\$738,175	\$572,349

As of December 31, 2017, the Company had net operating loss carryforwards for PRC tax purposes of approximately \$58.3 million which are available to offset any future taxable income through 2022. The Company also has net operating losses for United States federal income tax purposes of approximately \$5.1 million which are available to offset future taxable income, if any, through 2037.

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, 2017 for the mandatory deemed repatriation tax.

In assessing the realizability 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, 2017 and 2016. Therefore, the Company provided for a valuation allowance against its deferred tax assets of \$27,270,737 and \$21,452,802 as of December 31, 2017 and 2016, respectively.

The Company is also subject to 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 12 - 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 of directors.

### **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, 2017, there were 175,000 shares of restricted stock granted and outstanding under the Plan. No options were outstanding as of December 31, 2017 under the Plan.



**CHINA PHARM HOLDINGS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2017 and 2016**

There were no securities issued from the Plan during each of the years ended December 31, 2017 and 2016.

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, 2017 and 2016.

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, 2017, there was no remaining unrecognized compensation expense related to stock options or restricted stock grants.

**NOTE 13 – 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 14 – CONCENTRATIONS**

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.

For the year ended December 31, 2016, no customer accounted for more than 10.0% of sales and one supplier accounted for 21.1% of raw material purchases, one customer accounted for 46.3% of accounts receivable, and three different products accounted for 49.0%, 14.0% and 11.0% of revenue.