CHINA SKY ONE MEDICAL, INC.
Form 10-K
March 16, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2009

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

For the transition period from _____ to _____

Commission file number: 001-34080

CHINA SKY ONE MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Nevada	87-0430322
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
No. 2158, North Xiang An Road, Song Bei District, Harbin, People's Republic of China (Address of principal executive offices)	150028 (Zip Code)

Registrant's telephone number, including area code: 86-451-87032617 (China)

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

Title of each class	Name of each exchange on which registered
None	Not Applicable

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

Common Stock
(Title of Class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes o No x

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 reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of June 30, 2009, the aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $135,214,631, based on the last closing price of $13.48 per share, as quoted on the Nasdaq Global Market.

As of March 15, 2010, the registrant had 16,790,851 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

CHINA SKY ONE MEDICAL, INC.

ANNUAL REPORT ON FORM 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, together with other statements and information we publicly disseminate, contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and include this statement for purposes of complying with these safe harbor provisions.

Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, are generally identifiable by use of the words “believe,” “expect,” “intend,” “anticipate,” “estimate,” “project” or similar expressions. You should not rely on forward-looking statements since they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond our control and which could materially affect actual results, performances or achievements.

Factors that may cause actual results to differ materially from current expectations include, but are not limited to the “Risk Factors” discussed in Part 1, Item 1A of this Annual Report on Form 10-K. Accordingly, there is no assurance that our expectations will be realized. Except as otherwise required by the federal securities laws, we disclaim any obligations or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change our expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement is based.

The terms “the Company,” “we,” “us” and “our” refer to China Sky One Medical, Inc., together with our consolidated subsidiaries.

PART I

Item 1. Business.

General

We are engaged, through our China-based indirect subsidiaries described below, in the development, manufacture, marketing and sale of over-the-counter, branded nutritional supplements and over-the-counter plant and herb-based pharmaceutical and medicinal products. Our principal products are external use Traditional Chinese Herbal Remedies/Medicines, commonly referred to in the industry as "TCM." We have evolved into an integrated manufacturer, marketer and distributor of external-use TCM products sold primarily in the People's Republic of China ("China" or "PRC") and through Chinese domestic pharmaceutical chains. Recently, we have been expanding our worldwide sales effort as well. Prior to 2009, we sold both our own manufactured products, as well as medicinal and pharmaceutical products manufactured by others (the sale of third party products is referred to herein as "Contract Sales"). Commencing in 2009, we discontinued all of our Contract Sales as part of our revised strategic plan.

Corporate History

We are a Nevada corporation formed on February 7, 1986, formerly known as Comet Technologies, Inc. On July 26, 2006, after our acquisition of a China-based nutritional supplements business, we changed our name to "China Sky One Medical, Inc." We are a holding company doing business through American California Pharmaceutical Group, Inc., a California corporation ("ACPG"), our non-operating United States ("U.S.") holding company subsidiary, and ACPG's direct and indirect subsidiaries located in the People's Republic of China (the "PRC").

ACPG, was incorporated on December 16, 2003, under the name "QQ Group, Inc." QQ Group changed its name to "American California Pharmaceutical Group, Inc." in anticipation of the stock exchange transactions with our predecessor filer (then known as "Comet Technologies, Inc.") and Harbin City Tian Di Ren Medical Co., a company organized under the laws of the PRC ("TDR"), as further described below. On December 8, 2005, ACPG completed a stock exchange transaction with TDR and TDR's subsidiaries, each of which was a fully operating company in the PRC. In connection with this transaction, ACPG exchanged 100% of its issued and outstanding common stock for 100% of the capital stock of TDR and its subsidiaries.

Thereafter, on May 11, 2006, ACPG entered into a Stock Exchange Agreement (the "Exchange Agreement") with our shareholders. The transaction acquisition contemplated under the Exchange Agreement was consummated on May 30, 2006. As a result of this transaction, we issued a total of 10,193,377 shares of our common voting stock to the stockholders of ACPG, in exchange for 100% of the capital stock of ACPG. As a result, ACPG became our wholly-owned subsidiary.

TDR was originally formed in 1994 and its principal executive office is located in Harbin City, Heilongjiang Province, PRC. On December 29, 2000, TDR was reorganized and incorporated as a limited liability company under the "Corporation Laws and Regulations" of the PRC. At the time of TDR's acquisition by ACPG, in December of 2005, TDR had two wholly-owned subsidiaries, Harbin First Bio-Engineering Company Limited ("First") and Kangxi Medical Care Product Factory ("Kangxi"). In July, 2006, First and Kangxi merged, with First as the surviving subsidiary of TDR.

As of October 16, 2006, we organized Harbin Tian Qing Biotech Application Company as a wholly-owned PRC subsidiary of TDR ("Tian Qing"), to conduct research and development in the areas of tissue and stem cell banks, which is described in further detail below. As of December 31, 2009, Tiang Qing had no operating activities.

On April 3, 2008, TDR completed its acquisition of Heilongjiang Tianlong Pharmaceutical, Inc., a company organized under the laws of the PRC ("Tianlong"), that has a variety of medicines approved by the PRC's State Food and Drug Administration (the "SFDA") and new medicine applications, and which is in the business of manufacturing external-use pharmaceuticals. TDR previously acquired the Beijing sales office of Tianlong in mid-2006. In connection with this transaction, TDR acquired 100% of the issued and outstanding capital stock of Tianlong from its sole stockholder, in consideration for an aggregate purchase price of approximately $8,300,000, consisting of $8,000,000 in cash, and 23,850 shares of our common stock (valued at $12.00 per share).

On April 18, 2008, TDR consummated its acquisition of Heilongjiang Haina Pharmaceutical Inc., a company organized under the laws of the PRC ("Haina"), licensed as a wholesaler of TCM, bio-products, medicinal devices, antibiotics and chemical medicines. Haina did not have an established sales network and was acquired for its primary asset, a Good Supply Practice ("GSP") license (License No. A-HLJ03-010), issued by the Heilongjiang Province office of the SFDA as of December 21, 2006. The SFDA only issues such licenses to pharmaceutical resellers that maintain certain quality control standards. The GSP license will be up for renewal on January 29, 2012. In connection with this transaction, TDR acquired 100% of the issued and outstanding capital stock of Haina from its three stockholders in consideration for payment of approximately $437,000.

On September 5, 2008, TDR acquired Peng Lai Jin Chuang Pharmaceutical Company, a company organized under the laws of the PRC ("Peng Lai "), from its sole stockholder. Peng Lai, which has received Good Manufacturing Practice ("GMP") certification from the SFDA, was organized to develop, manufacture and distribute pharmaceutical, medicinal and diagnostic products in the PRC. In connection with this transaction, TDR acquired all of Peng Lai's assets, including, without limitation, franchise, production and operating rights to a portfolio of 20 medicines approved by the SFDA, for an aggregate purchase price of approximately $7,000,000 million, consisting of approximately $2,500,000 million in cash, and 381,606 shares of our common stock (valued at $12.00 per share).

Principal Products and Markets

We are engaged, through TDR, and its subsidiaries in the PRC, in the development, manufacture, marketing and sale of over-the-counter, branded nutritional supplements and over-the-counter plant and herb-based pharmaceutical and medicinal products. We have evolved into an integrated manufacturer, marketer and distributor of external use Chinese medicine products sold primarily to and through domestic pharmaceutical chains in the PRC. Historically, we handled sales of both our own manufactured products and Contract Sales of medicinal and pharmaceutical products manufactured by others. However, commencing in 2009, we discontinued all Contract Sales as part of our revised sales strategy.

With the exception of Peng Lai, which is located in Shan Dong Province, PRC, all of our manufacturing facilities are located in Heilongjiang Province, PRC. In addition, we have sales offices located in 24 provinces across China.

Our principal products are external use TCMs. Using various formulas, we produce a number of TCM products with several forms of delivery including ointments, sprays, medicated skin patches, injections, capsules, suppositories, tablets and granules. We also develop and sell bio-engineering products in the form of diagnostic kits, which are used for testing for different diseases. Over the next few years, we intend to concentrate much of our efforts on the development, production and sales of TCM products and testing kits, and antibiotic products.

Our principal operations are in the PRC, where TDR and its subsidiaries have manufacturing facilities and sales distribution channels covering most of the provinces in the PRC. Part of our sales strategy is to expand our worldwide sales by locating qualified distributors and sales agents outside of the PRC. Our overall revenues were approximately $130,092,000 in 2009, of which export overseas sales were approximately $10,121,000, accounting for approximately 7.8% of our total revenue. Overseas sales were $7,570,000 in 2008, accounting for approximately 8.2% of our total revenues. Overseas sales were $12,404,000 in 2007, accounting for approximately 25.2% of our total revenue in 2007.

All of our significant operations and long lived assets are located in the PRC. Below is a chart depicting our corporate organizational structure:

SFDA Licenses

The SFDA issues the licenses to manufacture and market pharmaceutical products in the PRC. Our licenses relate primarily to pharmaceutical production licenses, which are needed mainly for topical products, ointments and external test kits. TCM products also require a permit for sales, which permits are generally granted on a non-exclusive basis for four to five years depending on the product and subject to periodic review for renewal. For the year ended December 31, 2009, we commercialized 91 products through TDR and its subsidiaries. We have the necessary licenses and permits for all of our products.

Our TDR Subsidiary Owns the Following Subsidiaries in China

Harbin First Bio-Engineering

On September 26, 2003, TDR formed First under the laws of the PRC as its wholly owned subsidiary, with an authorized capital of approximately $1,460,000 (10,000,000 RMB). First focuses on research and development of the use of natural medicinal plants and biological technology products, such as our diagnostic kits. First, which officially commenced production on July 21, 2006, is one of the first companies in Heilongjiang Province conducting research and development of high technology biological products. First has two product lines:

- an enzyme immunity reagent kit product line; and
- a colloid gold product line.

Harbin Tian Qing Biotech Application

On October 16, 2006, TDR organized Tian Qing under the laws of the PRC as its wholly owned subsidiary, to conduct research and development in the areas of tissue and stem cell banks, which is described in more detail below. (See "Research and Development" below.) As of December 31, 2009, Tian Qing had no significant operations.

Heilongjiang Tianlong Pharmaceutical

On April 3, 2008, TDR completed the acquisition of Tianlong, which is in the business of manufacturing external-use pharmaceuticals. Tianlong's assets included, among other things, GMP certified manufacturing facilities, state-of-the-art manufacturing equipment, a research and development center, and production and operating rights to a portfolio of 69 medicines approved by the SFDA.

Heilongjiang Haina Pharmaceutical

On April 18, 2008, TDR consummated its acquisition of Haina, which is licensed as a wholesaler of TCM, bio-products, medicinal devices, antibiotics and chemical medicines. At the time of the acquisition, Haina did not have an established sales network and was acquired for its primary asset, a GSP license issued by the Heilongjiang Province office of the SFDA as of December 21, 2006. The SFDA only issues such licenses to resellers of medicines that maintain certain quality control standards. The GSP license will be up for renewal on January 29, 2012. Obtaining this license has enabled us to expand our sales of medicinal products without having to go through a lengthy license application process.

Peng Lai Jin Chuang Pharmaceutical

On September 5, 2008, TDR acquired Peng Lai, which received GMP certification from the SFDA, and was organized to develop, manufacture and distribute pharmaceutical products in the PRC. In connection with the acquisition of Peng Lai , TDR acquired all of Peng Lai's assets, including, without limitation, franchise, production and operating rights to a portfolio of 20 medicines approved by the SFDA.

Product Line

In 2009, we manufactured and marketed 91 products. Our manufacturing operations are conducted in our indirect subsidiaries' facilities located in Heilongjiang Province and Shan Dong Province in the PRC.

For the year ended December 31, 2009, we sold our products under five main categories:

- Patches (7 products);
- Ointments (18 products);
- Sprays (15 products);
- Diagnostic Kit (3 products);
- Others (48 products)

A description of our principle products, which generated a majority of our sales revenue in 2009, is as follows:

Patch Category:

Sumei Slim Patch

The Sumei Slim Patch is marketed and sold within and outside the PRC as a more natural treatment to lose weight. The Sumei Slim Patch uses Saponin as its major ingredient, and is effective in regulating and restraining the excessive secretion of certain hormones, while promoting others to foster weight loss as well as prevent weight gain.

Pain Relief Patch

A pain relief patch is designed to apply to the area of neck, shoulder, and waist. The patch is used for a number of ailments, including fever, headache, heart dysentery, diarrhea, and stiffness and pain caused by hypertension.

Anti-Hypertension Patch

The anti-hypertension patch is based on five thousand years of Chinese herbal vein therapy that has been adapted to a modern transdermal therapeutic system ("TTS"). The product utilizes a Body-Yong-Guan point technique, which is believed to maximize the effectiveness of the medicinal ingredients. The product is believed to stimulate blood capillaries and to be effective in improving circulation and reducing blood pressure.

Ointment Category:

Hemorrhoids Ointment

This product contains Acetate, Radix Notoginseng, and Rhizoma Coptidis. It is made in soft ointment form that is effective in sterilizing and relieving hemorrhoid symptoms, including itching, distending pain, burning, and bleeding.

Compound Camphor Cream

This product is made for the treatment of various pathogens on the skin surface and subcutaneously, such as mycete, trichopytic, staphylococcal bacteria aureus, bacillus coli, and candida albicans (thrush).

Spray Category:

Stomatitis Spray

This spray is used for the treatment of dental ulcers, pharyngitis, and faucitis. It is made with pure herbal medicines and, thus, has minimum side effects to human bodies.

Diagnostic Kit Category:

Cardiac Arrest Early Examination Kit

This product is used for early stage diagnosis of myocardial infarction (heart attacks).

Kidney Disease Testing Kit

The Urinate Micro Albumin Examination Testing Kit is used in connection with early stage diagnosis for primary kidney disease, hypertension and diabetes.

Other Product Category:

We include 48 of our products under the "Other" product category, because the categories of a pplications for these products do not separately represent a material amount of our revenues. The Other product category includes suppositories, eye drops, nasal drops, capsules, granules, injections, tablets and wash fluids.

Naftopidil Dispersible Tablet

This tablet is designed to treat benign enlargement of the prostate among males in their middle age. It is effective in its treatment because its ingredients can be easily digested and absorbed by the human body.

Naphazoline Hydrochloride Eye Drop

Naphazoline is recommended for the temporary relief of eye redness associated with minor irritations. This product can comfort the eyes by lubricating them and relieving such irritations.

Revenues by Product Categories

We believe that the most meaningful presentation of our products is by categories of method of delivery. Our total revenues during fiscal 2009, 2008, and 2007 were approximately $130,092,000, $91,816,000, and $49,318,000, respectively. The following table sets forth our principal product categories based on application type and the approximate amount and percentage of revenue from each of such product categories for the fiscal years ended December 31, 2009, 2008, and 2007:

	For the Years Ended December 31 ($ in thousands)					
	2009		2008		2007	
Product Category	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales
Patches	$40,770	31.3%	$35,484	38.6%	$19,609	39.9%
Ointments	28,862	22.2%	23,068	25.1%	3,270	12.6%
Sprays	18,499	14.2%	10,613	11.6%	8,742	18.7%
Diagnostic Kits	10,239	7.9%	8,781	9.6%	2,994	6.1%
Contract Sales	0	0.0%	5,655	6.2%	12,998	16.6%
Others	31,722	24.4%	8,215	8.9%	1,705	6.2%
Total	$130,092	100.0%	$91,816	100.0%	$49,318	100.0%

For a narrative description of the reasons for the changes in our revenue by product category over the past three years, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

Research and Development

We conduct all of our research and development ("R&D") activities either internally or through collaborative arrangements with universities and research institutions in the PRC. We have our own research, development and laboratory facilities located in the facilities of First and Tianlong. Our internal R&D team currently consists of 38 people. Many of our team members are professors affiliated with universities in the PRC.

Additionally, we have established several long-term partnerships with well-known universities and enterprises in the PRC. We have:

- Established a gene medicine laboratory for Small RNA project with Harbin Medical University; and
- Established a laboratory for Antroquinonol from Antrodia Camphorata with Taiwan Golden Biotechnology Corporation.

Under our partnership arrangements with universities and research institutions, we will generally hold the intellectual property rights to any developed technology. For example, as a result of our collaboration with Harbin Medical University, a product known as "Endostatin" is currently under development as a cancer suppressing product. Although this technology still bears the name of Harbin Medical University, we own the intellectual property rights pertaining to this technology. Additional information relating to this product and other products being developed is set forth under "Products Under Development" below and under the general product descriptions throughout this report.

We invested approximately $14,960,000, $7,413,000, and $3,158,000 in R&D for the years ended December 31, 2009, 2008, and 2007, respectively. Additional information about our R&D investments is included in the financial statements in Item 8 of this report (and notes thereto) and our "Management Discussion and Analysis on Financial Condition and Results of Operations" section below.

Products Under Development

The projects which accounted for a majority of our 2009 research and development expenses, grouped by subsidiary, are as follows:

TDR

Breast Cancer Technology

Hyperplasie Globulaire is the early stage of Hyperplasia of the Mammary Glands that has a high occurrence among females between twenty-five and forty-five years of age. Medicines with Endocrine can have significant side effects to the patient. Our Breast Cancer Technology is designed to effectively treat the Hyperplasie Globulaire with Traditional Chinese Medicine and with minimum side effects. We spent approximately $2,272,000, or 15.2% of total R&D expenditure in 2009, for efficacy testing, acute and long term toxicity testing.

Monoclonal Antibody Research

Monoclonal antibody is a bioactive substance produced when human cells identify and resist pathogenic intrusion from outside. Monoclonal antibody technology can produce large amounts of pure antibodies with desired substance. Tumor cells that can replicate endlessly are fused with mammalian cells that produce an antibody. The result of this cell fusion will continually produce antibodies. These antibodies are called monoclonal because they come from only one type of cell, the hybridoma cell. We believe Monoclonal antibodies have tremendous applications in the field of diagnostics, therapeutics, targeted drug delivery systems, not only for infectious disease caused by bacteria, viruses and protozoa, but also for cancer, metabolic and hormonal disorders. We spent approximately $965,000, or 6.5% of total R&D expenditure in 2009, for application and performance appraisal. As of December 31, 2009, we completed this project and are able to manufacture and commercialize these antibody materials.

Endostatin Research

Endostatin is a cancer treatment drug that works by “starving” cancer cells by restricting the generation of blood vessels around cancer lesions, thereby inhibiting, to a degree, the source of nutrients upon which the cancer cells survive. We have already completed teratogenicity testing, and have established quality standards for this drug. Further developments are underway to improve the product quality of Endostatin. We spent approximately $439,000, or 2.9% of total R&D expenditure in 2009, for acute and long term toxicity testing.

Patch Products

We spent approximately $1,820,000, or 12.2% of total R&D expenditure in 2009, for the optimization experiments of several patch products including slim patch, anti-hypertension patch, asthma patch, and pain relief patch. The optimization experiments are focusing on optimization of the extracted ingredients and irritation tests.

First

Diagnostic Kits

In 2009, we had 6 diagnostic kits under clinical trials. We spent approximately $2,727,000, or 18.2% of total R&D expenditure in 2009, on clinical trials for these 6 diagnostic kits.

Tianlong

Antroquinonol Extracted from Antrodia Cinnamomea

Antrodia Cinnamomea is well known in Taiwan as a traditional Chinese medicine. For several decades, it has been used in the treatment of food and drug intoxication, diarrhea, abdominal pain, hypertension, rashes, and liver and lung cancer. We have obtained an exclusive right to develop this technology with Taiwan Golden Biotechnology Corporation, which has completed pre-clinical research on Antroquinonol in the United Kingdom. The compound has been approved by the Food and Drug Administration in the U.S. to enter into first stage clinical trial. We spent approximately $387,000, or 2.6% of total R&D expenditure on this project in 2009.

Injections

In 2009, we had 3 injections under clinical trials. We spent approximately $1,944,000, or 13.1% of total R&D expenditure in clinical trials for these projects in 2009.

Peng Lai

We spent an aggregate of approximately $879,000, or 5.9% of total R&D expenditure in 2009, in optimizing effectiveness test for Naftopidil Dispersible tablets for prostate treatment, Sertraline Hydrochloride capsules for the treatment of mental depression, and Radix Isatidis granules and syrup to treat Influenza (flu).

Set forth below is a table of our major research and development projects, respective stage of development and applicable expenses for 2009:

Major Research and Development Expenses in Fiscal 2009
($ in thousands)

Projects	Stage	Expenses	% of total R&D
Diagnostic Kits - 6 products	Clinical trial	$2,727	18.2
Injections - 6 projects	Clinical trial	1,944	13.0
Breast Cancer Technology	Efficacy testing, Acute and Long Term Toxicity testing	2,272	15.2

Patches - 4 products	Extraction optimization testing	1,820	12.2
Monoclonal Antibody	Completed	965	6.5
Endostatin	Efficacy testing, Acute and Long Term Toxicity testing	439	2.9
Antroquinonol	Clinical trial	387	2.6
Radix Isatidis granule and syrup	Production process optimization	282	1.9
Naftopidil Dispersible tablets	Production process optimization	256	1.7
Sertraline Hydrochloride capsules	Production process optimization	249	1.7
Total		$11,341	75.8

(a) In fiscal 2009, we spent approximately $2,272,000 on our breast cancer technology, which represented approximately 15.2% of our total R&D expenditures. No other product represented 10% or more of our R&D expenses in fiscal 2009.

Total research and development expenses in fiscal 2009 were $14,960,000. The above listed projects comprise 75.8% of our total research and development expenses in fiscal 2009. The other projects and miscellaneous materials make up the remaining 24.2% of total research and development expenses for the year.

Set forth below is a table of our research and development expenses for fiscal 2008, classified by product category and stage of development:

		Stage of Development by Number of Projects and U.S. Dollar Amount ($ in thousands)						
Category		Application and Efficacy	Acute and Long Term Toxicity	Long Term Stability	Pending SFDA Approval	Supplemental Documentation	SFDA Approval	TOTAL
Bio-Engineering (a)	#	1 (b)	1 (c)	13	2	-	1	18
	$	$948	$1,192	$2,261	-	-	-	$4,401
Eye Drops	#	-	-	-	-	-	2	2
	$	-	-	-	-	-	$103	$103
Nasal Drops	#	-	-	-	-	-	1	1
	$	-	-	-	-	-	$61	$61
Injections	#	-	-	-	1	-	4	5
	$	-	-	-	$104	-	$510	$614
Spray	#	-	-	-	1	-	-	1
	$	-	-	-	$139	-	-	$139
Ointment	#	-	-	-	1	1	1	3
	$	-	-	-	$112	$90	$115	$317
Suppository	#	-	-	-	3	4	2	9
	$	-	-	-	$273	$352	$217	$842
Gel	#	-	-	-	-	2	2	4
	$	-	-	-	-	$293	$136	$429
Liquid	#	-	-	-	2	2	-	4
	$	-	-	-	$209	$210	-	$419
TOTAL	#	1	1	13	10	9	13	47 (d)
	$	$948	$1,192	$2,261	$837	$944	$1,142	$7,324 (e)

(a) Bio-engineering projects include our Endostatin cancer treatment drug, breast cancer drug and diagnostic kits. The diagnostic kits are designed for testing for different cancers and viruses, such as prostate cancer, stomach cancer, ovarian cancer, rectal cancer, liver cancer, Hepatitis B and C, human papilloma virus and mycoplasma virus. Diagnostic kits accounted for approximately 30.5% of total R&D expenditures in 2008.

(b) In fiscal 2008, we spent approximately $948,000 on research and development related to Monoclonal antibodies, which represented approximately 12.8% of our total R&D expenses. Monoclonal antibodies are a bioactive substance produced naturally when human cells identify and resist pathogenic intrusion from outside. Monoclonal antibody technology can produce large amounts of pure antibodies. Therefore, Monoclonal antibodies have tremendous applications in the field of diagnostics, therapeutics, and targeted drug delivery systems, not only for infectious disease caused by bacteria, viruses and protozoa but also for cancer, metabolic and hormonal disorders.

(c) In fiscal 2008, we spent approximately $1,192,000 on our Endostatin cancer treatment drug, which represented approximately 16.1% of our total R&D expenses. Endostatin is a cancer treatment drug that works by "starving" cancer cells by restricting the generation of blood vessels around cancer lesions, thereby inhibiting, to a degree, the source of nutrients upon which the cancer cells survive.

(d) Except as set forth in notes (b) and (c) above, no single project represented a material portion of our total R&D expenditures in fiscal 2008.

(e) Does not include costs for materials used in our R&D projects. Our total R&D expenditures for fiscal 2008 were approximately $7,413,000.

Cord Blood Stem Cell Bank

In 2006, we began implementing a plan to establish a cord blood stem cell bank in the PRC, for the treatment of various diseases such as leukemia, lymphoma and rebirth anemia. On October 16, 2006, the Health Department of Heilongjiang Province granted us, through Tian Qing, the exclusive right and license to become engaged in tissue and stem cell bank activities in Heilongjiang Province, PRC, through December 2010. Since the development of this project will require substantial managerial, technical and financial resources, and a number of significant risks, management is still evaluating the proper timing and strategy in launching this project.

Sales Approach

Over the past several years, we have continuously expanded our distribution channels for our products. As a result, we have established a sales network covering 24 provinces of mainland China, and have positioned sales managers and representatives in each of these markets.

In fiscal 2007, our sales model was focused on the creation of our own distribution channels. Therefore, we sold products directly to many small distributors and retail store locations. Commencing in fiscal 2008, we changed our business model and entered into distribution agreements with larger regional sales agents, who resell to smaller distributors and retail store locations. In addition, we entered into contracts with nationwide chain pharmacies. These changes to our product distribution channels resulted in our direct customer base decreasing from 943 customers at December 31, 2007 to 212 customers at December 31, 2009. Our change in sales strategy is further described in "Customers and Distribution" below.

We also managed to establish a marketing network through independent agents to develop an international market for our products. At present, our primary initial growth focus remains in the PRC. However, part of our sales strategy is to expand our sales outside of the PRC. Overseas sales accounted for approximately 7.8%, 8.2% and 25.2% of sales revenue for the fiscal years ended December 31, 2009, 2008 and 2007, respectively.

Materials and Suppliers

We employ purchasing staff with extensive knowledge of our products, who work with our marketing, product development, and formulations and quality control personnel to source raw materials for our products and other items. Raw materials are sourced principally in the PRC, and are generally available from a variety of suppliers. Harbin Zhong Jia Medicine Company and Heilongjiang Kangda Medicine Company accounted for approximately 16% and 42% of our total inventory purchases for the year ended December 31, 2009, respectively. Heilongjiang Kangda Medicine Company accounted for approximately 33% of our total inventory purchases for the year ended December 31, 2008. Harbin Yong Heng accounted for 23% of our total inventory purchases for the year ended December 31, 2007. No other suppliers accounted for 10% or more of our total inventory purchases in 2009, 2008, and 2007.

We seek to mitigate the risk of a shortage of raw materials, through identification of alternative suppliers for the same or similar raw materials, where available. We believe raw materials are available through alternative suppliers in the market place, if necessary. We manufacture bulk branded products to allow more extensive vertical integration and to improve the quality and consistency of raw materials.

Historically, we have signed agreements with suppliers that allowed us to hold extra raw materials at the cost of the suppliers. As a result, we could minimize our own inventory carrying costs, and improve our cash management, by keeping the inventory at the minimum level required to support our short-term sales. However, due to price increases for raw materials, and the related overhead costs for storing such raw materials, we started to increase our inventory levels toward the second half of 2009. In anticipation of continued price increases, management may further increase

our inventory levels in fiscal 2010.

Customers and Distribution

In fiscal 2007, our sales model was focused on the creation of our own distribution channels. Therefore, we sold products directly to many small distributors and retail store locations. In fiscal 2008, we changed our business model and entered into distribution agreements with larger regional sales agents, who resell to smaller distributors and retail store locations. In addition, we entered into contracts with nationwide chain pharmacies. Through the extensive sales networks, of these nationwide chains, we were able to reach all major metropolitan areas throughout the PRC. These changes to our product distribution channels resulted in our direct customer base decreasing from 943 customers at December 31, 2007 to 233 customers (not including branches of retail and drug supply chains) at December 31, 2008. As of December 31, 2009, we had 212 customers, not including branches of retail and drug supply chains.

The change in our sales strategy, which began in fiscal 2008, was initiated to improve product channel efficiencies, and to give us access to an increased number of ultimate purchasers. We believe that these changes will continue to lead to increased revenue by extending the reach of our distribution network. By reducing the number of customers we sell to directly, we have streamlined our accounts receivable management and collection and reduced channel distribution costs. These favorable cost variances have been partially offset by product price incentives we grant to the larger agents with which we have contracted.

For the year ended December 31, 2009, sales to Harbin Shiji Baolong Medicine Company and Shanxi Xintai Medicine Company accounted for approximately 16% and 11% of total revenues, respectively. Harbin Bao Da Medicine Company and Harbin Shiji Baolong Medicine Company accounted for approximately 16% and 14% of our accounts receivable in 2009, respectively. For the year ended December 31, 2008, sales to Shanxi Xintai and Harbin Shiji Baolong accounted for 15% and 12% of our total revenues, respectively. Harbin Shiji Baolong and Shanxi Xintai accounted for approximately 29% and 11% of our accounts receivable in 2008, respectively. For the year ended December 31, 2007, sales to Ning BoYue Hua Trading Company and Guang Zhou Xing He Trading Company accounted for approximately 14% and 11% of our total revenues, respectively. Hua Li Jiu Zhou Company accounted for approximately 11% of our accounts receivable in 2007. No other customers accounted for 10% or more of our total revenues or accounts receivable in 2009, 2008, and 2007.

In 2009, we implemented various initiatives toward promoting and marketing our products. Our advertising costs for the fiscal years ended December 31, 2009, 2008, and 2007 were approximately are $14,527,000, $7,299,000 and $4,385,000, respectively.

We will continue efforts to expand our markets into other provinces and larger cities in the PRC, and to other markets worldwide. Currently, our products are sold primarily in the PRC. In 2009, 2008 and 2007, approximately 92.2%, 91.8% and 74.8% of our revenues in were from the sale of products in China, respectively. Part of our sales strategy is to expand our worldwide sales. As a means of accelerating our distribution into other countries, we will seek to enter into strategic marketing arrangements with qualified firms that have distribution channels, brand name recognition, or other unique marketing strengths.

Competition

Competition in the TCM, pharmaceutical, and over-the-counter nutraceutical business is intense in China, and throughout the world. We compete with various firms, many of which produce and market products similar to our products, and many of which have greater resources than us in terms of manufacturing and marketing capabilities, management expertise and breadth, and financial wherewithal. Some of these competitors are far larger, have more resources then us and have stronger sales and distribution networks.

Our direct competitors are other domestic firms engaged in developing, manufacturing and marketing TCM and nutraceutical products. There are many of these companies in the PRC, in Heilongjiang Province, and even in the city

of Harbin.

We expect that the competition for medicinal products in the PRC and other world markets will become more intense over the next few years, both from existing competitors, and new market entrants. We will also face competition from foreign companies who may have established products, a strong proprietary pipeline and strong financial resources. Our management believes that we have certain competitive advantages in introducing new products to market due to key focus areas for development, our existing distribution channels, research and development capabilities and our relationship with certain universities and other research institutions. However, there can be no assurance that we will be able to compete and continue to grow in this highly competitive environment. Additional information relating to competition in the PRC can be found in the "Risk Factors" section below.

Government Regulation

Regulatory Environment

Our principal sales market is in the PRC. We are subject to the Pharmaceutical Administrative Law of the PRC, which governs the licensing, manufacturing, marketing and distribution of pharmaceutical products in the PRC, and sets penalties for violations. Our business is subject to various regulations and permit systems of the government of the PRC. Additionally, we are subject to government licensing rights and regulations, which relating to our stem cell R&D license. Permits we attain for TCM products are granted on a non-exclusive basis and are subject to periodical review for renewal.

The governmental approval process in the PRC for a newly developed health product can be lengthy and difficult. A product sample is first sent to a clinical testing agent designated by the Ministry of Health, which conducts extensive clinical testing and examination of the product to verify if it has the specified functions as stated by the company producing the product. A report will then be prepared and issued by the clinical testing agent confirming or negating such functions. After submittal to the agency, it generally takes six months to one year for a report to be issued by the testing agent. The report must then be submitted to a provincial Health Management Commission for approval. Following this submittal, a letter of approval issued by such commission will be submitted to the Ministry of Health for the issuance of a certificate that authorizes sale and marketing of the product in the PRC.

This entire process will generally take between eighteen months and two years. The approval process will depend to a certain extent on whether a specified product is a plant based pharmaceutical (“PBP”), or a plant based nutraceutical (“PBN”). PBPs are products composed of herbs, roots and plants that do not use synthetic chemicals, with certain medicinal functions for treatment of one or more illnesses. PBPs are generally prescription-based but in some cases may be sold over-the-counter. PBNs, also frequently known as “dietary supplements” or “nutritional supplements,” are also composed of herbs, roots and plants, but are essentially prophylactic or preventive in nature. All PBNs are available over-the-counter without a prescription. In the PRC, PBPs require the approval of the SFDA, while PBNs only require the approval of state and local governments prior to manufacturing and sale. Obtaining the approval from the SFDA is generally more complex and lengthy.

Because we and our subsidiaries are wholly-owned enterprises, we are subject to the law of foreign investment enterprises in the PRC, and the foreign company provisions of the Company Law of China, which governs the conduct of our wholly-owned subsidiaries and their officers and directors, and also limits our ability to pay dividends.

Compliance with Environmental Law

We comply with the Environmental Protection Law of the PRC, as well as applicable local regulations. In addition to compliance with the PRC law and local regulations, we consistently undertake active efforts to ensure the environmental sustainability of our operations. Because the manufacturing of herb and plant-based products does not generally cause significant damage or pollution to the environment, the cost of complying with applicable environmental laws is not material. In the event we fail to comply with applicable laws, we may be subject to penalties.

Intellectual Property

We own certain SFDA licenses for drug batch numbers and other proprietary technologies. Historically, we included our proprietary technologies and SFDA licenses for drug batch numbers within the category of patents. We now believe it is more accurate to categorize such intellectual property as SFDA licenses for drug batch numbers and other proprietary technologies.

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As of December 31, 2009, our intellectual property breakdown by SFDA licenses for drug batch numbers and other proprietary technologies is as follows:

IPs (Intangible Assets)	Year Acquired	Acquisition Cost $ in thousands	Reflected under Intangible Assets	Proprietary Technologies	Drug Batch Numbers
Endostatin	2006	$1,727	Yes	Yes	-
SFDA licenses for drug batch numbers	2008	$6,848	Yes	-	Yes
Monoclonal Antibody	2008	$5,106	Yes	Yes	-
Breast Cancer Technology	2008	$1,459	Yes	Yes	-
Antroquinonol	2009	$5,119	Yes	Yes	-
Small RNAs Technology	2009	$5,850	Yes	Yes	-

We purchased the rights to the patents for Endostatin and Antroquinonol, which are registered under the names of Harbin Medical University and Taiwan Golden Biotechnology Corporation, respectively.

We have acquired certain additional proprietary technologies from non-related third parties. The fair value of these proprietary technologies recorded in our financial statements are appraised periodically and amortized during its useful life.

As of the date of this filing, we own two registered patents for product packaging. As of December 31, 2009, these patents have nominal carrying values.

Under the PRC's State Protection Law, certain herbal medicine products, which have received approval from the SFDA, have automatic protection. SFDA licenses for drug batch numbers we acquired in connection with our acquisitions of Tianlong and Peng Lai in fiscal 2008 have been recorded as part of our intangible assets. We did not appraise or assign any value to the SFDA licenses for drug batch numbers developed internally by TDR or First.

We have registered "Kang Xi" as our trademark, which is used for all of our TCM products. The "Kang Xi" trademark was developed internally and registered by TDR before we became a public company. Our cost basis in the trademark is nominal.

Employees

The number of our employees has increased due to growth, increased research and development activities and expanded marketing and distribution efforts for our products. Our employees generally fall into the following categories:

By subsidiary company:

	Number of Employees	
Company	2009	2008
TDR	1,315	1,515
Tian Qing	0	0
First	107	97

Tianlong	207	97
Haina	399	24
Peng Lai	126	71
TOTAL:	2,154	1,804

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By nature of job:

	Number of Employees	
Type of Job	2009	2008
Executives and managers	201	146
Production and clerical	424	359
Sales and marketing	1,491	1,261
Research and development, technology	38	38
TOTAL:	2,154	1,804

As of December 31, 2008, we had 1,804 full-time employees. Our 2,154 employees, as of December 31, 2009, includes both 305 full time employees and 1,849 individuals hired on a contract basis through agencies. In 2009, we began hiring certain employees on a contract basis, in order to take advantage of cost efficiencies.

We do not have any employment agreements in place with our executive officers. None of the employees are covered by a collective bargaining agreement, however, we believe our relationship with employees is good.

Available Information

We file various reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on From 8-K, which are available though the SEC's electronic data gathering, analysis and retrieval system by accessing the SEC's home page (http://www.sec.gov). The documents are also available to be read or copied at the SEC's Public Reference Room located at 100 F Street, NE, Washington, D.C., 20549. Information on the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

We also make available free of charge through our website (www.cski.com.cn) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnishes it to, the SEC.

Item 1A. Risk Factors.

We are subject to certain risks and uncertainties as described below. These risks and uncertainties may not be the only ones we face. There may be additional risks that we do not presently know of, or that we currently consider immaterial. All of these risks could adversely affect our business, financial condition, results of operations and cash flows. Our business and operations may be adversely affected if any of such risks are realized. All investors should consider the following risk factors before deciding to purchase or sell our securities.

Risks Related to Our Business

Adverse economic conditions may harm our business.

In 2008, general worldwide economic conditions declined due to sequential effects of the sub prime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. This global economic downturn poses a risk as consumers and businesses may postpone spending, or seek new ways to eliminate spending, in response to these uncertain and challenging economic conditions. In addition, there could be a number of follow-on effects including foreign currency exchange rate fluctuations, insolvency of key suppliers and customer insolvencies. We cannot predict the timing or duration of any economic slowdown or recession or the timing or strength of a subsequent recovery, worldwide, or in the specific markets we serve. If the markets for our products significantly deteriorate due to these economic effects, our business, financial condition and results of operations may be materially and adversely affected.

Certain officers and directors have significant control over our company.

Liu Yan-qing and Han Xiao-yan, who are officers and directors of ours, also serve as officers and directors of ACPG, TDR and its subsidiaries. As of the date hereof, Dr. Liu and Ms. Han own, in the aggregate, approximately 36.5% of the issued and outstanding shares of our common stock. As a result, these shareholders are effectively able to control certain corporate governance matters requiring shareholders' approval. Such matters may include transactions in which they have an interest other than as a shareholder of ours, the approval of significant corporate transactions such as increasing the authorized number of our shares to complete acquisitions or raise capital, if necessary, and any other transactions requiring a majority vote without seeking other shareholders' approval. These persons also have the ability to control other matters requiring shareholder approval including our election of directors which could result in the entrenchment of management.

We depend on our key management personnel and the loss of their services could adversely affect our business.

We place substantial reliance upon the efforts and abilities of our executive officers, Liu Yan-qing, President, Chief Executive Officer and Chairman of the Board, Han Xiao-yan, Vice Chairman, and Stanley Hao, Chief Financial Officer and Secretary. We do not have employment agreements with these members of management. Accordingly, if any of these persons should leave the company, we would have no remedy or protections in place and would not be able to prevent them from competing with us or working for competitors. The loss of the services of any of these executive officers could have a material adverse effect on our business, operations, revenues or prospects. In addition, we do not maintain key man life insurance on the lives of these individuals.

Our expansion plan may not be successful.

Part of our strategy is to continue our growth through increasing the distribution and sales of our products by penetrating existing markets in the PRC, and entering new geographic markets in the PRC as well as Asia, the United States and other countries. However, many obstacles to entering such new markets exist, including, but not limited to,

international trade and tariff barriers, regulatory constraints, product liability concerns, shipping and delivery costs, costs associated with marketing efforts abroad and maintaining attractive foreign exchange ratios. Moreover, our expansion strategy may be based on incorrect assumptions and may be flawed, and may even damage our performance, competitive position in the market and, ultimately, even our ability to survive in the marketplace. We cannot, therefore, assure shareholders that we will be able to successfully overcome such obstacles and establish our products in any additional markets. Our inability to implement this growth strategy successfully may have a negative impact on our growth, future financial condition, results of operations or cash flows.

There are many safety risks involved in our products and services that could expose us to liability or inhibit our ability to secure insurance.

Our products and services involve direct or indirect impact on human health and life. The products we manufacture and sell may be flawed and cause dangerous side effects, and even fatality in certain cases, leading to major business losses and legal and other liabilities and damages to our company. In the event that any of our products are alleged to have adverse side effects, we could be subject to product liability claims. In addition to the threat of liability, there may be insurance costs if we enter into certain markets or may not be able to obtain insurance for certain products in some countries. Some distributors may refuse to sell our products in certain countries if they perceive such products to have a high risk or to be uninsurable.

We do not maintain any insurance and are exposed to all risks of loss, including resulting form product liability, property loss or damages, or other harm that we may cause to customers, vendors, suppliers and other third parties, or securities law claims.

We do not maintain liability or property insurance coverage or director and officer insurance coverage and, therefore, we are self-insured for all risks of loss. Although we seek to reduce potential liability through measures such as contractual indemnification provisions with distributors and suppliers, we cannot assure you that such measures will be enforced or effective. Our policy is to record losses associated with our lack of insurance coverage at such time as realized loss is incurred. Historically, we have not had any material losses in connection with our lack of insurance coverage and are not party to any material pending legal proceedings as of the date of this report. Management's intention is to use our working capital to fund any such losses incurred due to our exposure to inadequate insurance coverage. Our operating results could be materially and adversely affected if we were to pay significant damages or incur significant defense costs in connection with a claim.

We are highly dependent upon the public perception and quality of our products. Additionally, anti-corruption measures taken by the government to correct corruptive practices in the pharmaceutical industry could adversely affect our sales and reputation.

We are highly dependent upon consumers' perception of the safety and quality of our products as well as similar products distributed by other companies. Thus, the mere publication of reports asserting that such products may be harmful could have a material adverse effect on our business, regardless of whether these reports are scientifically supported.

The PRC government has recently taken anti-corruption measures to correct corrupt practices. In the pharmaceutical industry, such practices include, among other things, acceptance of kickbacks, bribery or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical distributors in connection with the prescription of a certain drug. Substantially all of our sales to our ultimate customers are conducted through third-party distributors. We have no control over our third-party distributors, who may engage in corrupt practices to promote our products. While we maintain strict anti-corruption policies applicable to our internal sales force and third-party distributors, these policies may not be effective. If any of our third-party distributors engage in such practices and the government takes enforcement action, our products may be seized and our own practices, and involvement in the distributors' practices may be investigated. If this occurs, our sales and reputation may be materially and adversely affected.

Our success will depend on our research and the ability to develop new products.

Our growth depends on our ability to consistently discover, develop and commercialize new products, and find new and improve on existing technologies, platforms and products. As such, if we fail to make sufficient investments in research, to be attentive to consumer needs, or fail to focus on the most advanced technologies, our current and future products could be surpassed by more effective or advanced products of other companies.

We currently rely on third parties to supply the key raw materials we use to produce our products.

Our business depends upon the availability of key raw materials. We rely on only external suppliers for these raw materials. In fiscal year 2009, Harbin Zhong Jia Medicine Company and Heilongjiang Kangda Medicine Company accounted for approximately 16% and 42% of our total inventory purchases, respectively. Heilongjiang Kangda Medicine Company accounted for approximately 33% of our total inventory purchases for the year ended December 31, 2008. For the 2010 fiscal year, we expect that our raw material suppliers will be substantially similar to last year and the amount of raw materials will increase commensurate with the increase in the demand of our products. If any of our major suppliers were to default or become unable to deliver the raw materials in sufficient quantities, we may be unable to purchase these raw materials from alternative sources on the same or similar terms, which could result in a significant decrease in our operating costs. In addition, any disruption in the supply of our raw materials could cause delay in the delivery of our products which would be harmful to our sales reputation and business. If supply is disrupted the increased amount we have to pay for raw materials could negatively impact our margins, cause us to cease production if an alternate supplier cannot be found. If we are unable to procure replacement supplies, our ability to meet the production demands of our customers could cause the loss of costumers and/or market share. Our financial results could be negatively impacted by the lost sales or decreased margins.

We are dependent on a limited number of customers for a significant portion of our revenues and accounts receivable and this dependence is likely to continue.

We have been dependent on a limited number of customers for a significant portion of our revenue. For the year ended December 31, 2009, sales to Harbin Shiji Baolong Medicine Company and Shanxi Xintai Medicine Company accounted for approximately 16% and 11% of total revenues, respectively. For the year ended December 31, 2008, sales to Shanxi Xintai and Harbin Shiji Baolong accounted for 15% and 12% of our total revenues, respectively. For the year ended December 31, 2007, sales to Ning BoYue Hua Trading Company and Guang Zhou Xing He Trading Company accounted for approximately 14% and 11% of our total revenues, respectively. Dependence on a few customers could make it difficult to negotiate attractive prices for our products and could expose us to the risk of substantial losses if any such customer stops purchasing our products. We expect that a limited number of customers will continue to contribute to a significant portion of our sales in the near future. Our ability to maintain close relationships with these top customers is essential to the growth and profitability of our business. If we fail to sell our products to one or more of these top customers in any particular period, or if a large customer purchases fewer of our products, defers orders or fails to place additional orders with us, or if we fail to develop additional major customers, our revenue would likely decline and our results of operations would be adversely affected.

In addition, our accounts receivable are concentrated among a small number of our customers. Harbin Bao Da Medicine Company and Harbin Shiji Baolong Medicine Company accounted for approximately 16% and 14% of our accounts receivable in 2009, respectively. Harbin Shiji Baolong and Shanxi Xintai accounted for approximately 29% and 11% of our accounts receivable in 2008, respectively. Hua Li Jiu Zhou Company accounted for approximately 11% of our accounts receivable in 2007. If any our customers fail to pay us on a timely basis, or do not pay us at all, our business, cash flow, financial condition and results of operations may be materially and adversely affected.

Significant competition from existing and new entities could adversely affect revenues and profitability.

We compete with other companies, many of which are developing and/or offering, or can be expected to develop and offer, products similar to ours. Our market is a large market with many competitors. Many of our competitors are more established than we are, and have significantly greater financial, technical, marketing and other resources than us. Some of our competitors have greater name recognition and a larger customer base. These competitors may be able to respond more quickly to new or changing opportunities and customer requirements and may be able to undertake more extensive promotional activities, offer more attractive terms to customers, and adopt more aggressive pricing policies. We cannot assure investors that we will be able to compete effectively with current or future competitors or that the competitive pressures we face will not harm our business.

We are subject to market and channel risks.

In fiscal year 2009, over 92% of our sales were made in the PRC, where we primarily sell our products through drug chain stores. Because of this, we are dependent to a large degree upon the success of our PRC-based distribution channel, as well as the success of specific retailers in the distribution channel. We rely on these distribution channels to purchase, market, and sell our products. Our success is dependent, to a large degree, on the growth and success of the drug stores, which may be outside our control. There can be no assurance that the drug store distribution channels will be able to grow or prosper as they faces price and service pressure from other channels, including the mass market. There can be no assurance that retailers in the drug store distribution channel, in the aggregate, will respond or continue to respond to our marketing commitment in these channels.

We may have difficulty in defending intellectual property rights from infringement.

Our TCM products are generally not protected by patents but by trade secrets. Certain TCM license agreements are made on a non-exclusive basis. Our success depends, in large part, on our ability to protect current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market similar products. We have filed patent applications seeking to protect newly developed and/or technologies. Some patent applications in the PRC are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by many months, we may not be the first to invent, or file patent applications on any of its discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to or licensed by us may not provide competitive advantages for its products. Patents that are issued may be challenged, invalidated or circumvented by competitors. Furthermore, our patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

To the extent that we market products in other countries, we may have to take additional action to protect our intellectual property. The measures we take to protect our proprietary rights may be inadequate, and we cannot provide any assurance that our competitors will not independently develop formulations and processes that are substantially equivalent or superior to our products or copy our products.

We also rely on trade secrets, non-patented proprietary expertise and continuing technological innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Moreover, trade secrets and proprietary technologies may otherwise become known or be independently developed by competitors. If patents are not issued with respect to products arising from research, we may not be able to maintain the confidentiality of information relating to these products.

We will be subject to risks relating to third parties that may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the pharmaceutical and nutraceutical industries with respect to the manufacturing, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to commence or defend against charges relating to the infringement of patent or proprietary rights. Any such litigation could involve or result in:

- the incurrence of substantial expense, even if we are successful in the litigation;
- a diversion of significant time and effort of technical and management personnel;
- the loss of our rights to develop or make certain products; and
- the payment of substantial monetary damages or royalties in order to license proprietary rights from third parties.

Although patent and intellectual property disputes within these industries have often been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. These arrangements may be investigated by regulatory agencies and, if improper, may be invalidated. Also, the required licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent our company from manufacturing and selling some of our products or increase costs to market these products.

In addition, when seeking regulatory approval for some of our products, we are required to certify to regulatory authorities, including the SFDA that such products do not infringe upon third party patent rights. Filing a certification against a patent gives the patent holder the right to bring a patent infringement lawsuit against us. Any lawsuit would delay regulatory approval by the SFDA. A claim of infringement and the resulting delay could result in substantial expenses and even prevent us from manufacturing and selling certain of our products.

The launch of a product prior to a final court decision or the expiration of a patent held by a third party may result in substantial damages to us. Depending upon the circumstances, a court may award the patent holder damages equal to three times their loss of income. If we are found to infringe a patent held by a third party and become subject to such treble damages, these damages could have a material adverse effect on our results of operations and financial condition.

Our failure to comply with accounting policies and regulations in making reasonable estimates and judgments could negatively impact our financial position and results of operation.

We are subject to critical accounting policies and actual results may vary from estimates. We have followed, and will continue to follow, generally accepted accounting principles for the United States in preparing financial statements. As part of this work, we must make many estimates and judgments concerning future events. These affect the value of the assets and liabilities, contingent assets and liabilities, and revenue and expenses reported in such financial statements. We believe that these estimates and judgments are reasonable, and we have made them in accordance with accounting policies based on information available at the time. However, actual results could differ from estimates, and this could require us to record adjustments to expenses or revenues that could be material to our financial position and results of operations in the future.

Our business is subject to many governmental regulatory and policy risks.

Our business must be conducted in compliance with various government regulations and in particular, the SFDA's regulations. Government regulations may have material impact on our operations, increase costs and could prevent or delay the manufacturing and selling of our products. Research, development, testing, manufacturing and marketing activities are subject to various governmental regulations in China, including health and drug regulations. Government regulations, among other things, cover the inspection of and controls over testing, manufacturing, safety and environmental considerations, efficacy, labeling, advertising, promotion, record keeping and sale and distribution of pharmaceutical products. We will not be able to license, manufacture, sell and distribute the vast majority of our products without a proper approval from government agencies and in particular the SFDA. This approval process is lengthy, with approvals for TCM products typically occurring 18-24 months after the application is initially filed. There is no assurance that we will obtain such approvals on a timely basis, or at all. Delays in obtaining approvals will delay our ability to market products and denial of approval for a specific product will result in our inability to market the product and recoup the expenses incurred in that products development and testing.

In addition, delays or rejections may be encountered based upon additional government regulation from future legislation, administrative action or changes in governmental policy and interpretation during the period of product development and product assessment. Although we have, so far, obtained the rights to sell our products in the PRC, we may not continue to receive and maintain regulatory approvals for the sales of these products. Our marketing activities are also subject to government regulations with respect to the prices that it intends to charge or any other marketing and promotional related activities. Government regulations may substantially increase the costs for developing, licensing, manufacturing and selling products, impacting negatively our operations, revenue, income and cash flow.

There could be changes in government regulations towards the pharmaceutical and nutraceutical industries that may adversely affect our business.

The manufacture and sale of pharmaceutical and nutraceutical products in the PRC is heavily regulated by many state, provincial and local authorities. These regulations significantly increased the difficulty and costs involved in obtaining and maintaining regulatory approvals for marketing new and existing products. Our future growth and profitability depends to a large extent on our ability to obtain regulatory approvals.

The SFDA has implemented new guidelines for licensing of pharmaceutical products. All existing manufacturers with licenses, which are currently valid under the previous guidelines, were required to apply for the GMP certifications by June 30, 2004, and to receive approvals by December 31, 2004. We received certifications for our current products. However, should we fail to maintain the GMP certifications under the new guidelines in the future, or for new products, our businesses would be materially and adversely affected.

Moreover, the laws and regulations regarding acquisitions of the pharmaceutical and nutraceutical industries in the PRC may also change and may significantly impact our ability to grow through acquisitions.

We need to manage growth in operations to maximize our potential growth and achieve our expected revenues.

Our success depends on our ability to achieve continued growth. In order to maximize potential growth in current and potential markets, we believe that we must expand our manufacturing and marketing operations. This expansion will place a significant strain on management and operational, accounting and information systems and will require substantial additional capital. We will need to continue to improve financial controls, operating procedures, and management information systems if and as we grow. We will also need to effectively train, motivate, and manage our employees. A failure to manage our growth could disrupt operations and ultimately prevent us from generating the revenues we expect.

International operations require our company to comply with a number of U.S. and international regulations.

We are required to comply with a number of international regulations in countries outside of the United States. In addition, we must comply with the Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies or their agents and employees from providing anything of value to a foreign official for the purposes of influencing any act or decision of these individuals in their official capacity to help obtain or retain business, direct business to any person or corporate entity or obtain any unfair advantage. Any failure to adopt appropriate compliance procedures and ensure that our employees and agents comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties and/or restrictions in our ability to conduct business in certain foreign jurisdictions. The U.S. Department of The Treasury