

China Blood Products Industry Report, 2010

Nov/2010



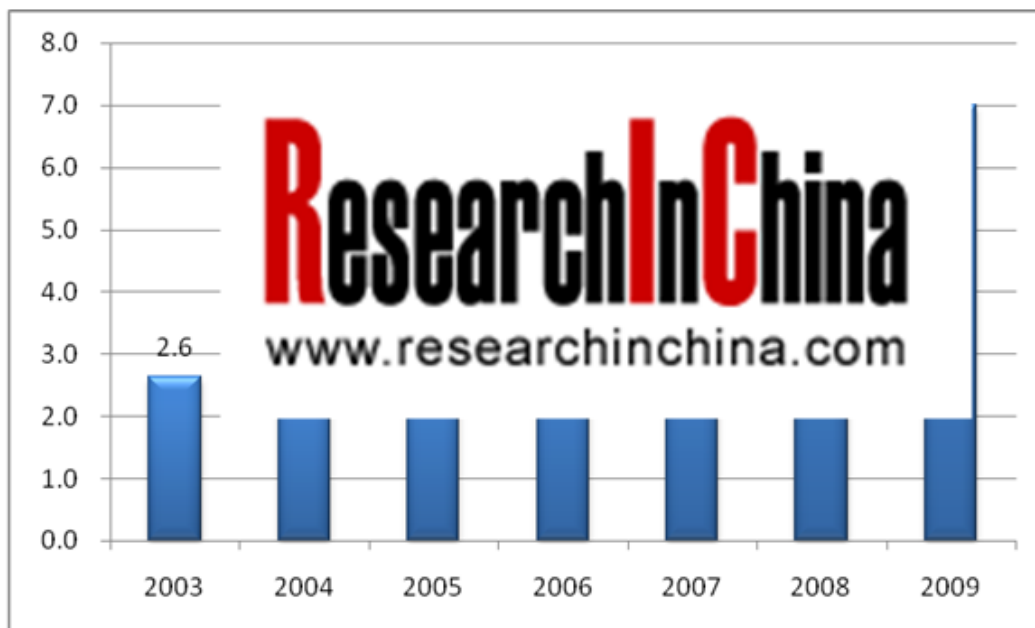
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2. Overview of China Blood Products Industry

2.1 General Overview

China sees a growing demand for blood products in the downstream market. The supply drain mainly contributes to the following reasons: firstly, China has a large population base and the ageing population indicates expanding blood products consumers; secondly, the improved safety performance of blood products pushes for the market expansion. In 2009, the market scale of blood products industry of China approximated RMB ** billion, and it is expected to get further increased in the upcoming 2 or 3 years.

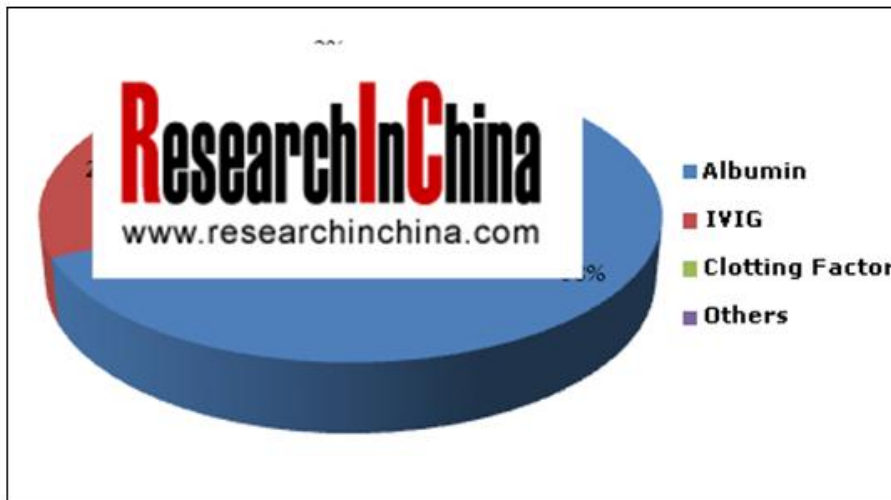
Blood Products Market Scale in China, 2003-2009 (RMB bn)



Source: Southern Medicine Economic Research Institute; ResearchInChina

In 2009, the blood products of China constituted **% albumin, **% IVIG and 9% clotting factor. China is a country with a lot of HBV victims. And there are 24 million cirrhosis cases in this country. And the unavailable substitute for albumin results in the robust demand for albumin, with the ex-factory price on par with the highest retail price. Additionally, the medical treatment level of China still falls behind that causes people have a limited knowledge to IVIG and clotting factor.

Product Structure of Blood Products in China, 2009



Source: ResearchInChina

Different from China, the proportion of clotting factor, albumin and IVIG in 2009 was **%, **% and 25% respectively in the foreign consumption structure. For developed countries, they tend to give priority to prevention, which leads to huge demand for clotting factor and the likes.

Product Structure of International Blood Products, 2009

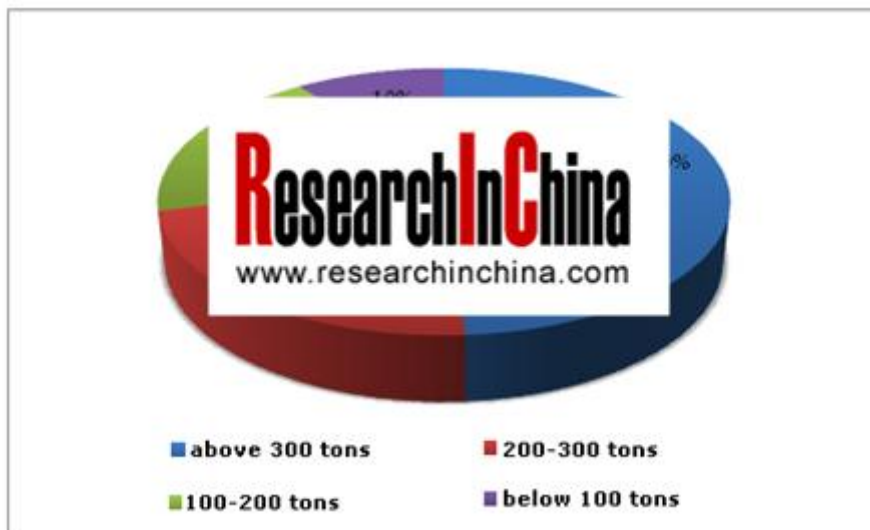


Source: ResearchInChina

As for demand, China, like other developing countries such as India and Brazil, is still at the low-level stage in spite of huge population. The very limited consumption of blood products makes it possible for China to embrace an emerging potential.

In the long term, the short supply of blood plasma worldwide is inevitable. In 2009, the consumption of albumin in China’s urban areas leveled out the developed countries in Europe and America, with the per capital consumption of 0.2g. While in the rural areas of China, the figure was no more than 0.005g, lagging far behind the urban market. In another word, the overall albumin consumption in China averages 0.07g, falling short of the developed countries. But alongside with the increased income and health care awareness, the consumption gap is bridging. Likewise, the IVIG consumption in developed countries is 10kg/mln people, while it is 1kg/mln people in China, an equivalent of 10%.

Market Shares of Blood Products Manufacturing Enterprises in China, 2009



Source: WIND; ResearchInChina

By the end of 2009, there were a total of ** blood products manufacturers in China passing the GMP authentication and only ** of them are operating. A few of the ** manufacturers, like Hualan Biological Engineering, Beijing Tiantan Biological Products, Shanghai RAAS Blood Products, Sichuan Yuanda Shuyang Pharmaceutical, China National Biotec Group and Shanghai Institute of Biological Products, with the annual plasma volume exceeding ** tons, accounted for **% of the total in the country. And another 5 manufacturers produced 200 ~300 tons of blood products annually, contributing **% of the total in the country.

Product Lines Contrast of Blood Products Manufacturing Enterprises in China

Products	Hualan Biological Engineering	Shanghai RAAS Blood Products	Beijing Tiantan Biological Products	China National Biotec Group	Sichuan Yuanda Shuyang Pharmaceutical	Shanghai Institute of Biological Products
Human Immunoglobulin for Intravenous Injection	√	√	√	√	√	√
Human Albumin	√	√	√	√	√	√
Human Immunoglobulin	√		√	√	√	√
Human Tetanus Immunoglobulin	√		√	√	√	
Human Hepatitis B Immunoglobulin	√		√	√	√	√
Human Rabies Immunoglobulin	√			√	√	
human Clotting factors VIII	√	√	√			
prothrombin complex contrates	√	√	√			
human fibrinogen	√	√	√			√

Source: ResearchInChina

Release Volume of Blood Products in China, 2007-Aug. 2010

Products	Unit	2007	2008	2009	2010.1-8
Human Immunoglobulin for Intravenous Injection (2.5g/bottle)	1,000 bottles	**	**	**	**
Human Rabies Immunoglobulin	1,000 bottles	0	2526.00	**	**
Human Immunoglobulin	1,000 bottles	0	**	1632.45	**
prothrombin complex contrates	1,000 bottles	0	**	**	**
Clotting Factor VIII	10,000 bottles	0	**	**	**
Human Albumin (10g/bottle) including home-made and imported products	1,000 bottles	6400.66	**	**	**
	1,000 bottles	**	6581.45	**	**
	1,000 bottles	1166.85	**	**	**
Human Tetanus Immunoglobulin	1,000 bottles	0	**	**	**
human fibrinogen	1,000 bottles	0	**	**	**
Human Hepatitis B Immunoglobulin	1,000 bottles	0	2038.87	**	1511.41

Source: NICPBP; ResearchInChina

2.2 Operating Environment

2.2.2 Policies

The release of Management Regulations on Blood Products issued by the State Council in December 1996 meant that China tried to standardize its management of blood product industry. In the year end of 1997, the blood product industry started to implement GMP authentication, and was the first sub-sector in the pharmaceuticals industry to practice GMP standard. Fortunately, many leading manufacturers passed GMP authentication in succession 4 years later. In 2001, China announced that it would refuse to approve new blood product manufacturers to access the industry and establish entry barrier.

In the beginning of 2004, the state intensified its control on plasma collection. In 2006, China issued Work program on the Transformation of Plasma Collection Stations, according to which, it regulated that plasma collection stations should be acquired by blood product manufacturers in order to form "one-to-one" plasma supply relationship; Particularly, the county-level administrative departments were not allowed to establish plasma stations; During the course, the blood product manufacturers with "one-to-one" supply relationship held the priority to acquire; If no agreement was accepted by both sides in due time, other blood product manufacturers were allowed to involved in the acquirement via auction.

The whole blood product industry chain was reshuffled though the transformation, making it possible for blood product manufacturers to control every node of the industry chain. Meanwhile, new polices placed some related enterprises and plasma stations under the supervision and control of SFDA and Health authorities at all levels, cutting the benefit chain linking with local medical administrations and plasma stations, effectively improving the quality control level in the overall industry chain.

Major Policies for Blood Products in China

Names	Date of Release	Sources	Contents
Circular Notice on Banning to Import Blood Products Such as VIII Factor	1986	Ministry of Health	Except human serum albumin, others are not allowed to import in China
Blood Products Management Regulations	1996	General Office of the State Council	.standardizing the management of China's blood products
China's Action Plan for Containment and Prevention of AIDS	2001	General Office of the State Council	New blood product manufacturers were not allowed to approve to be established since 2001.
Circulation on Pilot Release Work of Biological Products	2001	State Drug Administration	4 kinds of vaccines included in EPI allowed by the state, hepatitis B vaccine, human bold albumin and 4 kinds of in-vitro diagnostic reagents for blood screening use were given priority to be issued by batch.
Release of Biological Products Management Measures	2002	State Drug Administration	Since January 15th, 2003, biological products that not been issued are not allowed to be sold or imported, and those products which fail to reach the standard in the process of issuing are also not allowed to be sold.
Work program on the Transformation of Plasma Collection Stations	2006	9 ministries including Ministry of Health	"One-to-one" plasma supply relationship should be established between plasma station and blood product manufacture.
Notice On The Implementation of Quarantine Period of Blood Plasma Products, Raw Materials For Production	2007	State Drug Administration	asking manufacturers to build source plasma quarantine period system
Plasma Collection Stations Management Approaches	2008	Ministry of Health	Only manufacturers with above 6 kinds of products are allowed to build plasma stations and, meanwhile, new technology standard on plasma station was also established.

Source: ResearchInChina

2.2.3 Domestic Biopharmaceutical Market

In the past decades years, the biologically pharmaceutical industry of China has made great progress. To date, China has more than ** biological and biochemical pharmaceutical manufacturers, the total sales revenue of which approximated RMB ** billion in 2009, and the combined growth rate of which during 2005-2009 realized **%.

Sales Revenue and YoY Growth Rate of Biological and Biochemical Pharmacy in China, 2005-2009



Source: WIND; ResearchInChina

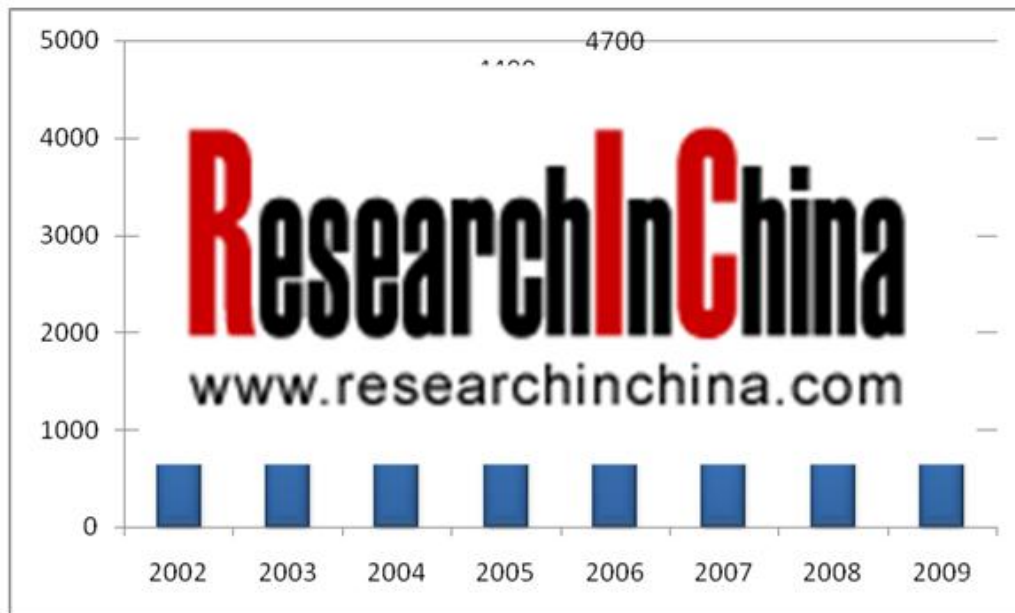
2.3 Plasma Volume

The global blood products manufacturers feature small quantities and large scales, with the plasma volume maintaining ** tons. The annual plasma volume of blood products worldwide approximates ** tons at present.

In 2002, the plasma volume of blood products in China reached 3,000 tons. There was a slight growth in plasma volume in 2004 and 2005 because of the reshuffle of plasma stations. In 2006, the plasma volume was close to 4,700 tons. In 2007, plasma stations in China were confronted with restructure and, meanwhile, in response to the call from the Ministry of Health, plasma stations were forced to passed GMP authentication, which led a an overwhelming majority of plasma stations closed or would-be closed. In 2008, affected by "window quarantine period", the plasma volume in China was only ** tons, and it picked up to around ** tons until 2009 while the blood products were still short of supply.

The estimation shows that the market competition will loom large when the plasma collection volume reaches ** tons. Supposing the average industrial growth remains at **%, it needs about 3-4 years to realize the balance between supply and demand.

Annual Plasma Volume in China, 2002-2009 (ton)



Source: ResearchInChina

The blood product enterprises can be classified 3 types by scale and product category: the first is represented by Hualan Biological Engineering, Shanghai RAAS Blood Products, Beijing Tiantan Biological Products, China National Biotec Group; the second refers to the enterprises that have 4-10 plasma stations and single production line, but hold monopolized advantages in local regions; the third refers to a dozens of enterprises with no advantages both in production line and plasmas station.

According to the provision of the Ministry of Health, the mid-and small-enterprises with the product quantity below 6 types are not allowed to build plasma stations, which means that the first type manufacturers have the possibility to expand by their advantage in scale and, for the second type, they may have to face the fate to be acquired; And the third-layer manufacturers will be gradually weeded out.

Production of Blood Products Manufacturing Enterprises in China, 2009

Company	Location	Plasma Volume	Volume of Available Plasma
Hualan Biological Engineering	Henan	**	**
Shanghai RAAS Blood Products	Shanghai	**	**
Beijing Tiantan Biological Products	Sichuan	**	**
Sichuan Yuanda Shuyang Pharmaceutical	Sichuan	**	**
Shanghai Institute of Biological Products	Shanghai	**	**
Guiyang Qianfeng Biological Product	Guizhou	**	**

Source: Enterprise Announcements; ResearchInChina

2.4 Import & Export

According to the China Customs, the tax ID of blood products which have not import or export record are usually under the codes of 30029090 and 30021000.

The export value of people blood, animal blood products for medical, other toxin and culture organism with the tax ID of 30029090 realized USD ** million, up **% year-on-year. These products are mainly exported to 31 countries and regions including HK, India, US, Japan and UK, with the proportion of **%. In particular, **% of these blood products are exported to HK. China has a total of such ** manufacturers targeting foreign markets. In terms of export value, Lanzhou Biotechnique Development, Sichuan Kelun Biomedical, Novozymes, B & M and Beijing Diertajin Biotechnologies were the top 5, with the proportion of **%.

The export value of antiserum and other blood & modified immunological products with the tax ID 30021000 was USD ** million, an increase of **% over 2008. These products are mainly exported to 115 countries and regions including India, US, Canada, Ethiopia and Thailand, with the proportion of **%. In particular, 31.5% of these products are exported to India. China has ** such manufacturers targeting foreign markets. In terms of export value, Ai De Diagnostics, Shanghai RAAS Blood Products, **, ABON and ** were the top 5 in 2009, with the proportion of 62.2%.

The import value of people blood, animal blood products for medical, other toxin and culture organism with the tax ID of 30029090 realized USD ** million, up **% year-on-year.

3. Main Blood Product Markets

3.1 Human Serum Albumin

Human Serum Albumin (HSA) is a kind of blood product which is extracted from human plasma. In clinic, it is an indispensable agent for emergency or significant operations, and the patients who suffer a variety of severe diseases and need nutrition and protein emergently. HSA is applied widely.

The HSA consumption in China was about 150 tons in one full year. The HSA consumption in China was about 120-130 tons in 2006 and less ** tons in 2007, because since 2006, China has reformed plasma collection stations, which causes the shortage of raw plasma and unsaturated production of blood products companies.

There is a big gap of HAS consumption between China and developed countries, and market demand is huge as well. In terms of albumin usage level, it is nearly equal between China's urban citizens and the developed countries such as the United States and Europe, while the use of blood products such as albumin for rural citizens are in serious lack, only 0.005g per capita. It is expected that the demand for HSA in China will maintain steady growth with annual growth margin of 10%-15%.

In addition to meet clinical demand, albumin is also promising as medium and protective agent for the production of vaccines. The consumption for vaccine manufacturers amounts to ** tons, of which around ** tons are for rabies vaccine per year. With the improvement of people's living level and successively output expansion of vaccine manufacturers, plus extension of China's basic immunization projects and people's idea enhancement in disease prevention, the demand for vaccine has increased year by year. The leading vaccine manufacturers have successively expanded their output and increased the demand for medium albumin, thus it is forecasted that the demand for medium albumin will reach ** tons in five years. This will further aggravate the shortage of albumin. In addition, many biological drug production processes and final products all require albumin as protective agent. As a medium, HSA market will further expand with huge development potentials.

Major Manufacturers and Their Shares in Chinese Human Serum Albumin Market, 2009



Source: National Institute for the Control of Pharmaceutical and Biological Products; ResearchInChina

Plasma has abundant albumin, and the separation and purification process is relatively simple, so HSA can be obtained easily, many companies can produce it. By release volume in 2009, top three enterprises only imported HAS, and their market shares amounted to **%. The concentration degree of HSA market was not high. Hualan Biological Engineering Ltd took a leading position in China with **% market shares.

The albumin consumption of urban people in China is nearly same with that in developed countries. In the future, there will be little space for the development of albumin market. HSA is still the most important product among blood products in China. There are two reasons for wide application of albumin in Chinese blood products. First, hepatitis prevails in China. It needs albumin to treat hepatitis; this situation will not disappear with the maturity of blood products market. Second, blood products market is immature and doctors have limited knowledge about rational application scope; this situation will disappear with the maturity of blood products market.

As countries have made more restrictions on the entry to the industry, the albumin which comes from human serum has been in shortage. Therefore, a variety of genetic products which substitute plasma products have emerged or are about to come out. The number of traditional plasma products manufacturers in developed countries (such as Japan, some developed countries in Europe and America) is declining, and these enterprises have turned to genetic products. Chinese blood-borne hepatitis B vaccine and interferon enterprises have also turned to genetic products. The United States and Japan are investing a huge sum of fund in accelerating the commercial production of genetic albumin. All in all, it is imperative for China to speed up the development and production of genetic recombination albumin.

3.2 Intravenous Human Immunoglobulin

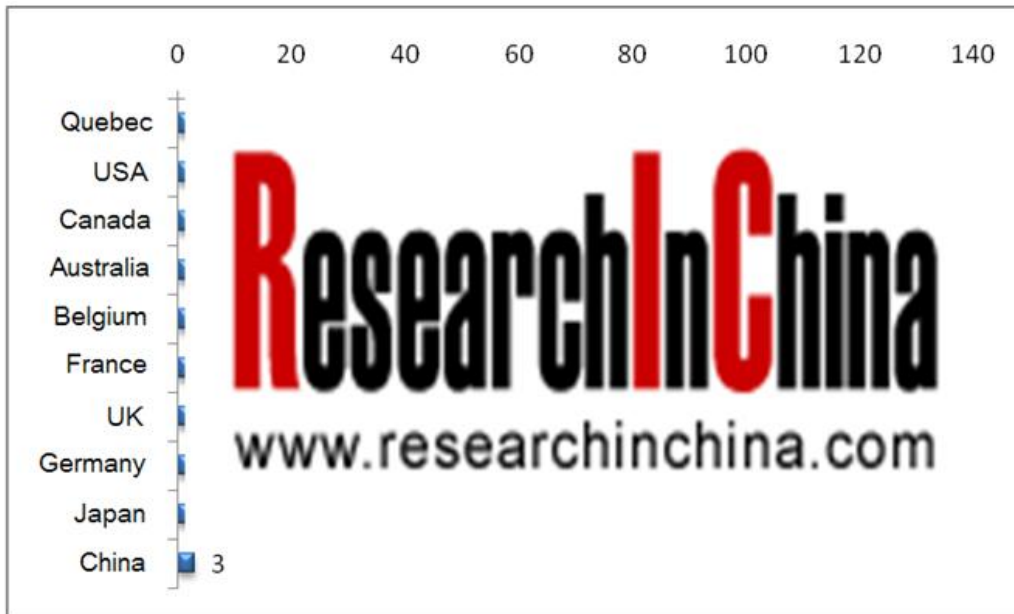
Major Manufacturers and Their Shares in Chinese Intravenous Human Immunoglobulin Market, 2009



Source: National Institute for the Control of Pharmaceutical and Biological Products; ResearchInChina

Due to the state administrative ban, all of Intravenous Human Immunoglobulin products are produced by Chinese enterprises. In 2009, Intravenous Human Immunoglobulin Market presented a relatively dispersed pattern; Shandong Taibang Biological Products Co. Ltd, Rongsheng Pharmaceuticals, Guiyang Qianfeng Biological Product Liability Co., Ltd ranked top three, with **% market shares totally. China's per capita consumption of Intravenous Human Immunoglobulin is much lower than the international average level. In the future, the growth rate of Intravenous Human Immunoglobulin will be likely to exceed the average level.

Per Capita Consumption of Intravenous Human Immunoglobulin in Some Countries and Regions, 2005 (g/1000 persons)



Source: National Blood Authority; ResearchInChina

3.6 Human Prothrombin Complex

Major Manufacturers and Their Shares in Chinese Human Prothrombin Complex Market, 2009



Source: National Institute for the Control of Pharmaceutical and Biological Products; ResearchInChina

There are a small number of Human Prothrombin Complex manufacturers. By release volume, Human Prothrombin Complex Market has a high concentration degree in 2009, only Hualan Biological Engineering Ltd (**%), Shanghai RAAS Blood Products Co., Ltd (**%) and Shanghai Xinxing Medicine Co., Ltd (**%) were approved to release Human Prothrombin Complex. Human Prothrombin Complex is effective to hemorrhage incurred by the shortage of coagulation factors II, VII, IX and X. Human Prothrombin Complex Market is promising.

4. Key Manufacturers in China

4.2 Shanghai RAAS Blood Products Co., Ltd

4.2.1 Profile

Shanghai RAAS Blood Products Co., Ltd is a joint venture established by RAAS and Blood Products and Blood Transfusion Equipment Operation Company of Shanghai Blood Center in October 1988. It's the first large blood products joint venture in China.

Shanghai RAAS is mainly engaged in the production and sales of blood products, vaccines, diagnostic reagents and testing equipment and testing technology and provides testing services. Its main products include human serum albumin, intravenous human immunoglobulin (pH4), human coagulation factor VIII, human prothrombin complex concentrate, human fibrinogen, lyophilized human thrombin, surgical lyophilized fibrin sealant, a total of 7 varieties and 23 specifications.

4.2.2 Operation

Operating Income and Net Income of Shanghai RAAS Blood Products Co., Ltd, 2006- H1 2010

(Unit: RMB mln)



Source: Corporate Annual Report; ResearchInChina

The company achieved operating income of RMB**million and net income of RMB** million in 2009, up **% and **% year on year, mainly due to the recovery growth in the company’s plasma investment volume and the rise in the product prices.

In the first half of 2010, the company achieved operating income of RMB** million and net income of RMB** million, up **% and **% year on year respectively, mainly due to the enhanced gross margin caused by increased plasma investment volume and prices.

Release Volume of Blood Products of Shanghai RAAS Blood Products Co., Ltd, 2007- Aug. 2010

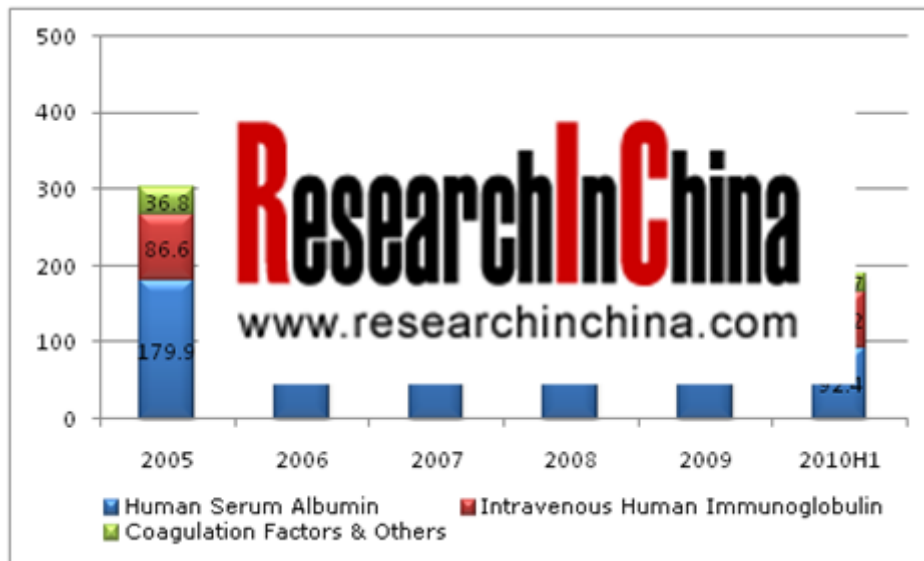
(Unit: 1,000 bottles)

Product	Specification	Lot release volume in 2009	Lot release volume in the first eight months of 2010
Human serum albumin	10g/50ml bottle	**	**
Intravenous human immunoglobulin (Ph4)	2.5g,50ml/ bottle	**	**
Human coagulation factor VIII	200IU/bottle	**	**
Human fibrinogen	0.5g/ bottle	**	**
Human prothrombin complex	200IU/ bottle	**	**

Source: National Institute of Food and Drug Control; ResearchInChina

In the first eight months of 2010, the lot release volume of Shanghai RAAS’ human serum albumin was close to nearly two times of the lot release volume in the whole year of 2009, while the lot release volume of intravenous human immunoglobulin reached over two times of the lot release volume in the whole year of 2009.

Operating Income of Shanghai RAAS Blood Products Co., Ltd (by Product), 2005- H1 2010 (Unit: RMB mln)



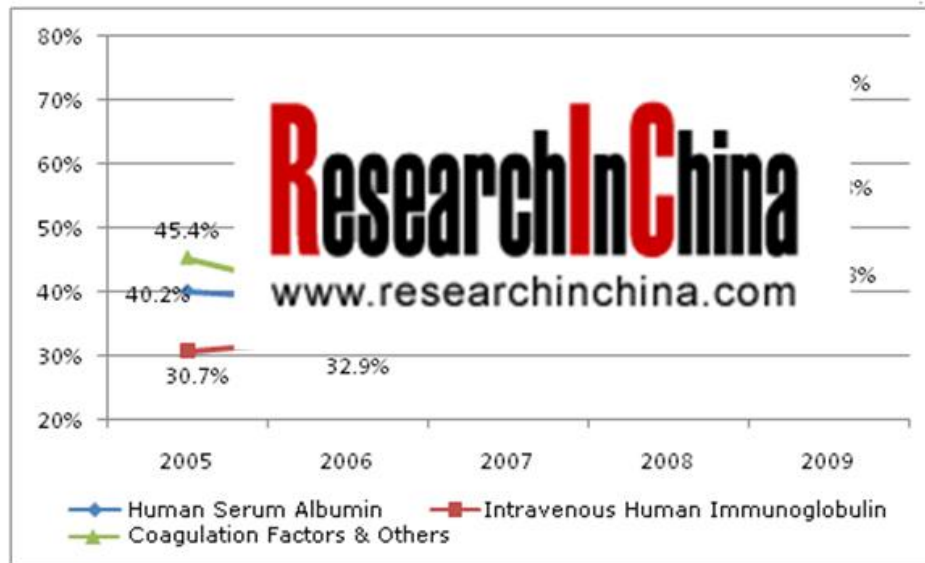
Source: Corporate Announcement; ResearchInChina

Albumin and intravenous human immunoglobulin are the main source of revenue for the company, which collectively accounted for **% and **% of the company's main business income in 2008 and 2009 respectively. Intravenous human immunoglobulin has seen larger price rise in the recent years, with significantly improved profitability.

In October 2009, Shanghai will increase the maximum retail price (by 300 units) of coagulation factor VIII from the original RMB** to RMB**, up **%. The price has been implemented in other regions of the country;

In February 2010, Shanghai will increase the maximum retail price (by 2.5g) of intravenous gamma globulin from the original RMB420 to RMB**, up **%; the ex-factory price from RMB402 to RMB**. Most of the country has adjusted the prices accordingly.

Gross Margin of Shanghai RAAS Blood Products Co., Ltd (by Product), 2005-2009



Source: Corporate Announcement; ResearchInChina

New Product - Hepatitis B Immunoglobulin will be Available Soon

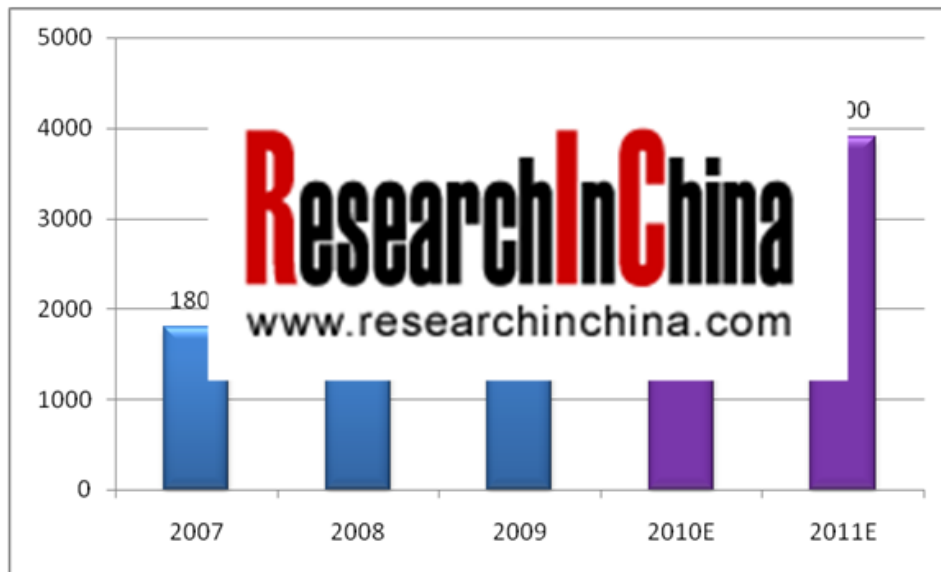
The company's R&D of hepatitis B immunoglobulin is in clinical phase 3. Upon completion of the phase, the company will file the product for approval. The launch of hepatitis B immunoglobulin will bring new benefits to the company.

The Company's Plasma Collection Volume Growth Rate is higher than the Industry Average

In 2009, the industry average growth rate of plasma collection volume was about **% in 2009, and the company's was close to **%, which was higher than the industry average, mainly due to the company's reasonable distribution of plasma collection stations, with most of plasma collection stations distributed in populated and relatively underdeveloped regions with poor transport conditions.

The company currently has nine plasma collection stations, located in regions including Hunan, Guangxi and Shaanxi. By the end of 2009, the company had got three stations approved in Baoting County, Qiongzong County and Baisha County of Hainan Province, which will commence operation in 2011. In 2009, the average plasma volume of single plasma collection station was about **tons, up **% compared to ** tons in 2007. However, the plasma contributors in the approved plasma collection regions of the company's plasma collection stations are distributed unevenly, most of them concentrate in the vicinity of the plasma stations, and few of them are distributed in nearby counties and towns. Therefore, there is huge market development potential. In the first half of 2009, the company mobilized the enthusiasm of plasma contributors by enhancing the nutrition payments, which had achieved good results. The company's number of registered plasma contributors increased from ** people at the end of 2008 to over ** people at the end of 2009, and the annual average times of plasma collection increased from nine times in 2008 to ** times in 2009, which is far from the upper limit of ** times stipulated by the state, so the market potential is huge.

Plasma Volume of Shanghai RAAS Blood Products Co., Ltd, 2007-2011E (Unit: 1,000 tons)



Source: Corporate Announcement, ResearchInChina

Operating Income of Shanghai RAAS Blood Products Co., Ltd (by Region), 2008-2009 (Unit: RMB mln)



Source: Corporate Announcement; ResearchInChina

4.2.3 Strategies

1. Developing Gene Recombination Products and Ending Plasma Raw Materials Restrictions

The company is marching towards the field of gene recombination, and has finished the development of technology roadmap for coagulation factor VIII. The first stage of laboratory research has finished, and pilot research is being conducted. The company has become a pioneer in the R&D of high-end blood products.

Upon success of the R&D, the company can rid itself of the restrictions on the plasma investment volume, and expand production independently to completely relieve the supply crunch in domestic coagulation factor market. Shanghai RAAS is one of the two only enterprises capable of producing coagulation factor VIII and human prothrombin complex. It basically has occupied an advantageous position in the domestic coagulation factor market.

2. Exploring Overseas Markets

The company exports products to more than 20 countries and regions overseas, accounting for about 15% of the company's sales revenue. It will focus on developing overseas markets to ensure the company's performance in the future.

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