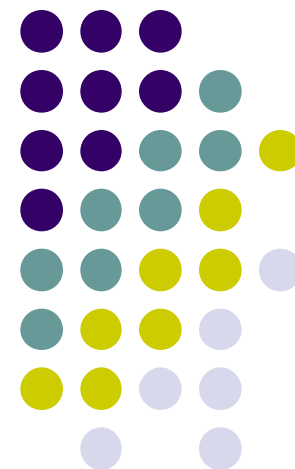


3SBio Inc.

2007 CIBC Annual Healthcare
Conference

David Chen, VP Business
Development

November 5, 2007



Company Overview

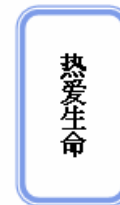


3SBio Inc. is a leading, fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China

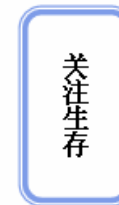
- Therapeutically focused in oncology and nephrology markets
- 6 marketed products and 6 pipeline products under development
 - EPIAO, the flagship product, is the No.1 EPO product in Chinese market since 2002*
 - TPIAO, the first protein-based TPO therapeutic product approved in Chinese market
 - Multiple late-stage development programs
- Compelling revenue and profit growth
 - 3 Year ended 2006 net revenue CAGR: 20.5%
 - YoY net revenue growth of 49.2% for second quarter 2007
 - YoY Net Income Growth of 268.9% for second quarter 2007
- Company Facts:
 - Founded in 1993
 - Headquarter & manufacturing facilities: Shenyang
 - Sales headquarter: Beijing
 - Employees: 373 (as of June 30, 2007)
 - NASDAQ IPO on February 7, 2007
 - A total of 21,726,308 ADSs and 152,084,155 common shares were outstanding*
 - 39% public float, include 8,452,140 ADSs and 59,164,980 common shares*
 - Investor information at: www.3SBio.com



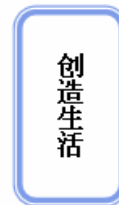
Cherish Life



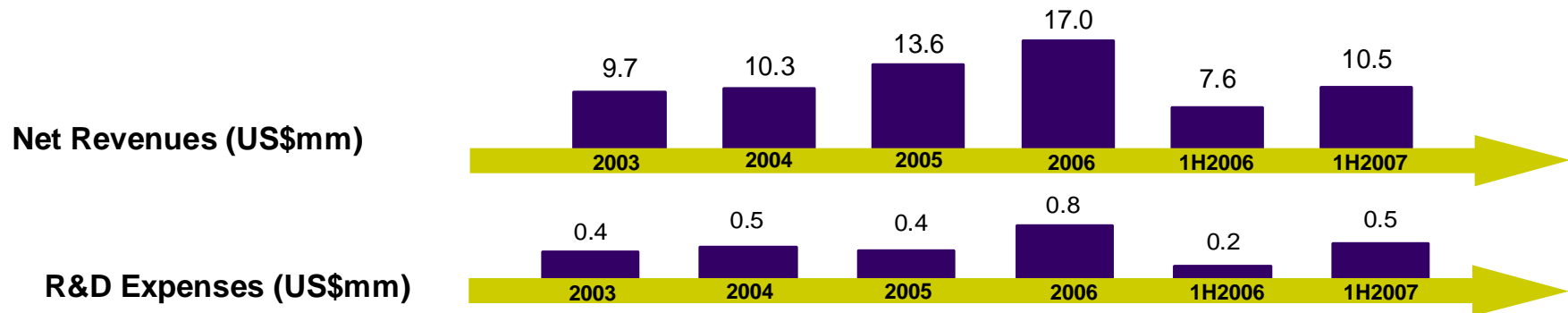
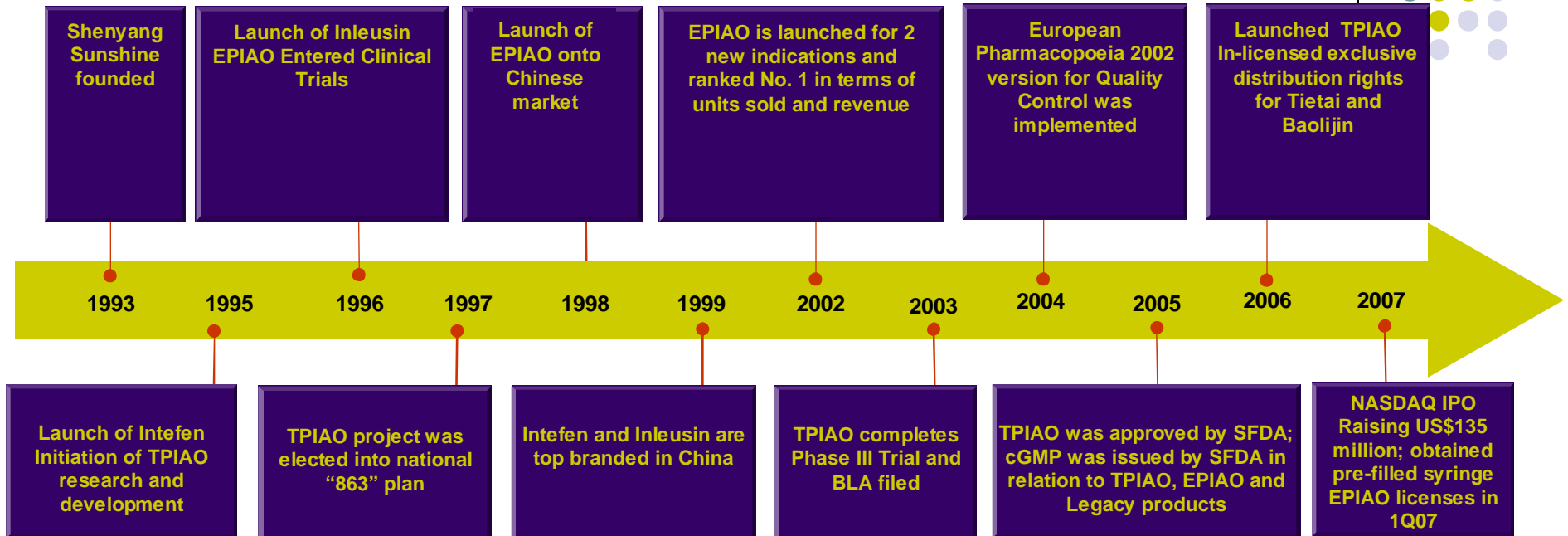
Care for Life



Create Life



Company History





Investment Highlights

1

The Leading Biotechnology Company Built on a Solid Operational Foundation in the Most Rapidly Growing Pharmaceutical Market



Nationwide Sales, Marketing, and Distribution Network



Proven Research and Development Capabilities and Deep Pipeline of Product Candidates



High-quality, Proprietary Manufacturing Processes With Significant Cost Advantages



Experienced and Market Oriented Management Team

2

Strong Financial Performance with Growth and Profitability

3

Synergistic Portfolio of Marketed Products and Late Stage Pipeline with Leading Market Share and Exclusivity in Key Market Segments

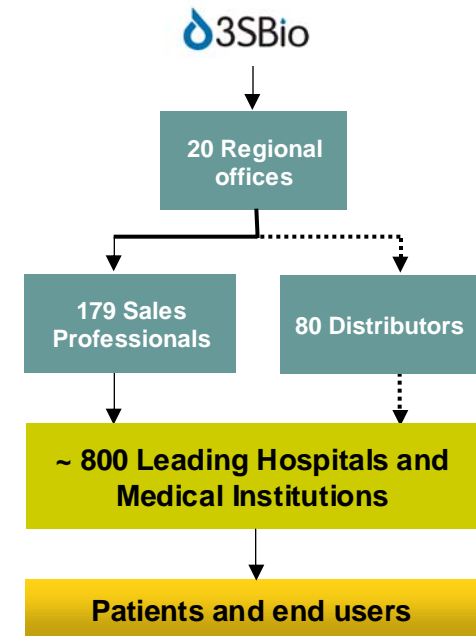
4

Clear and Focused Growth Strategy



Established Nationwide Sales and Marketing Network

We currently distribute our products in 18 provinces and the key major cities throughout China



We are executing on our strategy to grow our sales and marketing infrastructure to meet China's rapidly growing demand for our products

Proven Research and Development Capabilities



Proven Track Record of Product Development & Commercialization

- Successfully developed and commercialized four protein-based therapeutics in China to date
- Proven ability to identify and in-license complementary product opportunities, which our sales force could effectively market and grow sales
- Market driven product development effort with the goal of addressing large markets with significant unmet medical needs in oncology and nephrology

Highly experienced R&D professionals

- 20 research personnel and medical professionals, 7 with advanced degrees and many with extensive experience in the healthcare and biotech research fields

Productive working relationship with the SFDA

- Our productive working relationship with the SFDA is critical when seeking regulatory approvals for new therapeutics in China

Manufacturing and Facilities Overview



- State-of-the-art facility covering 3,000 square meters including a 1,600 square meter clean room
- cGMP certified manufacturing facility and voluntary applications of European Pharmacopoeia standards
- Composed of three departments including mammalian cell genetic engineering, bacterial genetic engineering, and formulation divisions
- High-end name brand equipment including bioreactors, centrifuges, chromatography systems and lyophilizers
- Significant capacity to accommodate substantial growth from key products
 - Phase I of the new plant is expected to complete by the end of 2007
 - Upgrade of other facilities to be EMEA compliance is expected to be near completion in 2008
- Received the government award for R&D and manufacturing capability
 - “Model Manufacturing Base” – awarded by the Ministry of Science and Technology of the People’s Republic of China



Experienced and Market-Oriented Management Team

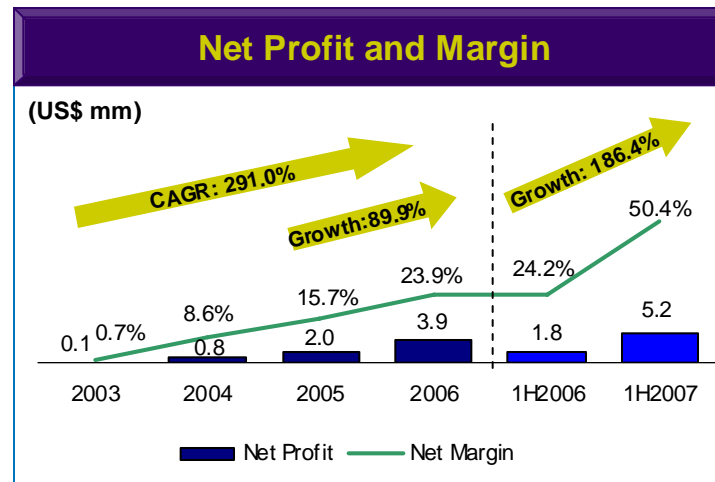
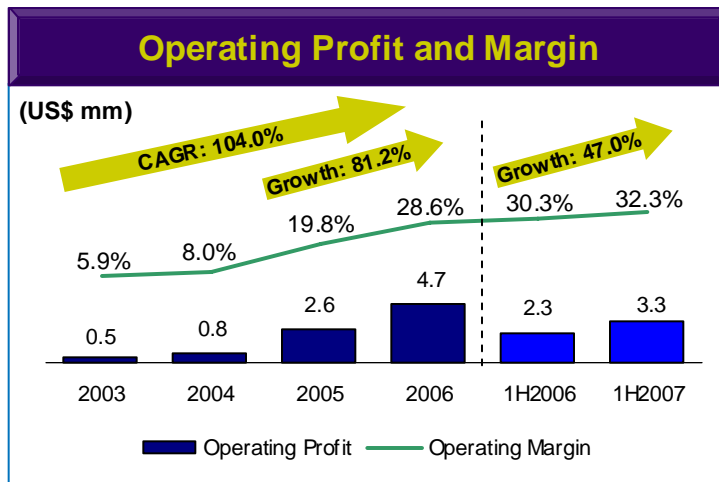
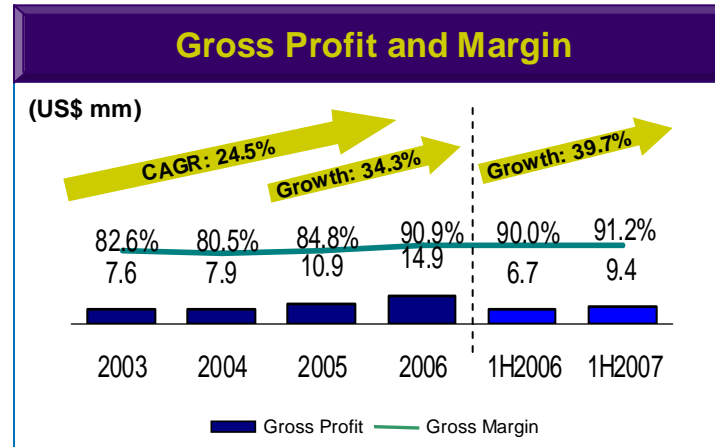
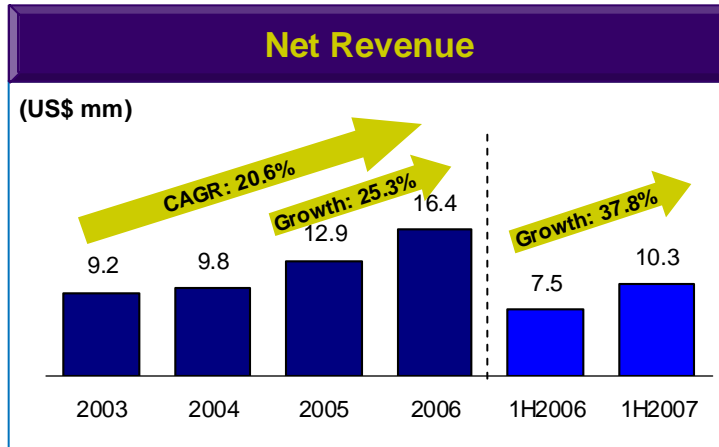


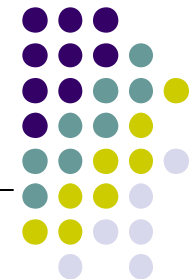
Our management team has extensive experience in China's biopharmaceutical industry and a solid understanding of both Chinese and international industry best practices

<p>Jing Lou, M.D., Ph.D. <i>CEO and Director</i></p>	<p>Has been with 3SBio since 1995, and built 3Sbio into the Chinese leading biopharmaceutical company. Has more than 10 years' pharmaceutical industry experiences. Post-doctoral training at NIH; and Ph.D. from Fordham Univ. in Molecular and Cellular Biology</p>
<p>Clara Mak, MBA, CA, CPA <i>CFO</i></p>	<p>Joined 3SBio in 2006. Possesses more than 7 years of private equity experience in Asia and has extensive audit and financial advisory experiences with Arthur Andersen, Deloitte & Touche in Canada and Price Waterhouse in Hong Kong. CPA in US and CA in Canada. MBA from University of Toronto</p>
<p>Yingfei Wei, Ph.D. <i>CSO</i></p>	<p>CSO since 2006. Responsible for 3SBio's Research and Development, partnership, and technology division. Former R&D research director of Bayer in San Francisco, and former senior research scientist at Human Genome Sciences. Post-doctoral fellow at Harvard and Ph.D. from University of California</p>
<p>David Chen, MD, MBA <i>VP of Business Development</i></p>	<p>Joined in 2007. Responsible for pursuing strategic business opportunities and external alliances and partnerships with biotechnology and pharmaceutical companies in major markets. A former medical doctor, held various management positions in multinational pharmaceutical companies in the US, including GlaxoSmithKline and Eli Lilly & Company.</p>
<p>Dongmei Su, MSc. <i>CTO</i></p>	<p>Joined in 1993. In charge of the 3SBio's manufacturing, processing engineering. Co-inventor of several of 3SBio's patents. Masters in Microbiology and Pharmacology, and BSc in Biochemical Engineering from Jilin University</p>
<p>Ke Li, MSc., MBA <i>Regulatory</i></p>	<p>Joined in 1993. Responsible for all corporate and regulatory matters. MBA from Liaoning University, and BSc in Engineering from Jilin University</p>



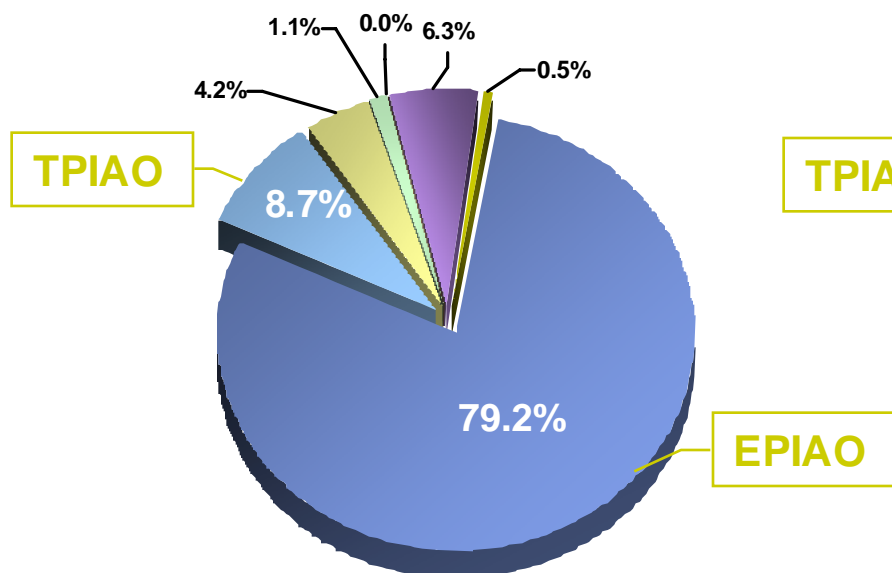
Operational Efficiency and a Track Record of Growth and Profitability



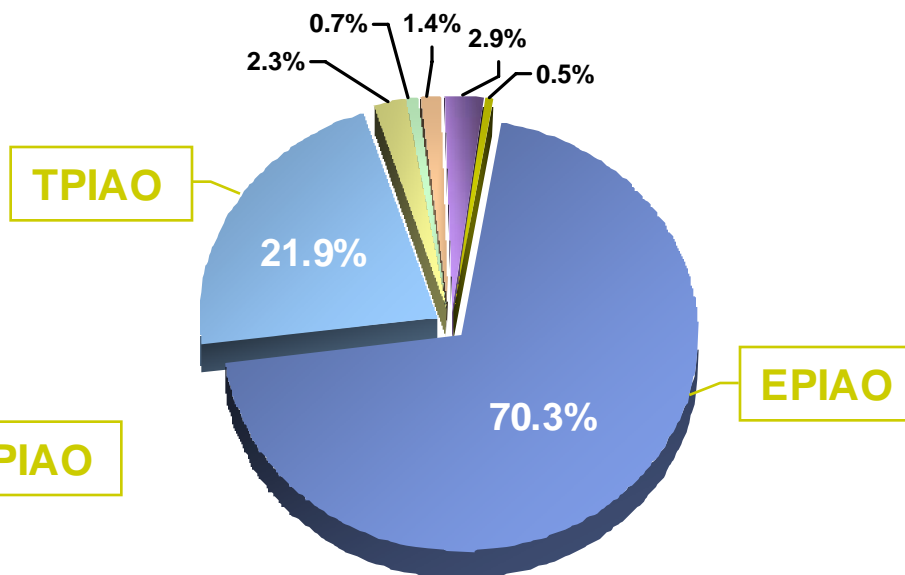


Key Revenue Drivers – EPIAO & TPIAO

1H 2006



1H 2007



■ EPIAO ■ TPIAO ■ Intefen ■ InLeusin ■ Tie Tai ■ Export ■ Others



EPIAO – Our Flagship Product

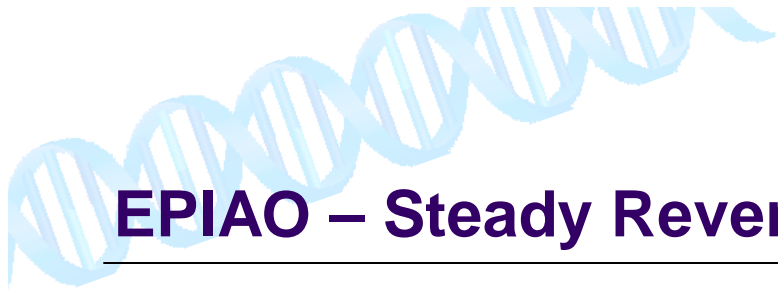
EPIAO (益比奥) is an injectible recombinant human erythropoietin (rhEPO) that stimulates the production of red blood cells in patients with anemia and reduces the need for blood transfusions

Key Highlights

- Market leading EPO product in terms of both revenue and volume since 2002
- 3 Year EPIAO Revenue CAGR: 29.7%
- 8 year of post-marketing experience and ~7mm vials sold
- Only EPO approved for three distinct medical indications
 - Anemia associated with chronic renal failure
 - Anemia associated with chemotherapy
 - Red blood mobilization before, during, and after surgery
- Strong brand recognized for quality and reliability
- Competitive pricing – less than 1/3 of its imported comparables produced overseas
- Only EPO product in China that has been approved for use in cancer patients
- One of the only domestic 10,000 IU available
- Line extension strategy
 - Pre-filled syringe EPO under EPIAO brand name Launched in 2Q
 - High dose EPIAO for cancer indication

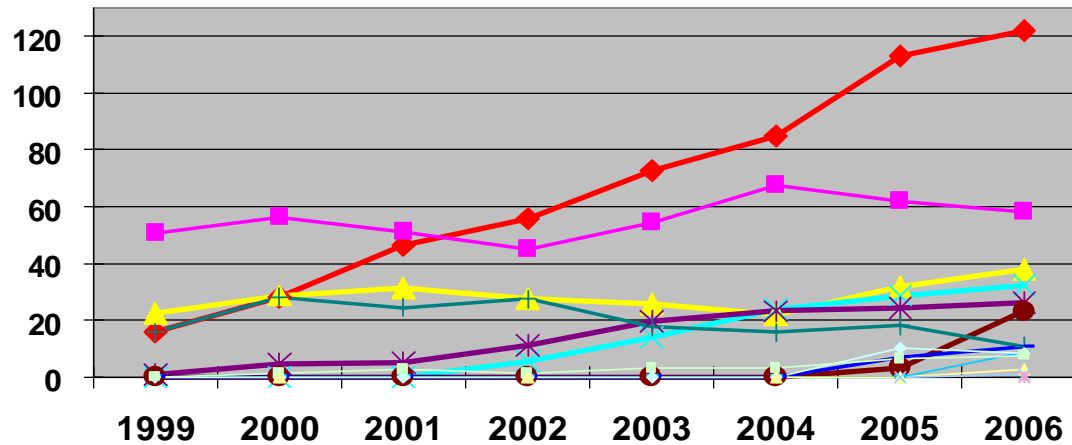
益比奥®
EPIAO® (rHuEPO)
重组人红细胞生成素





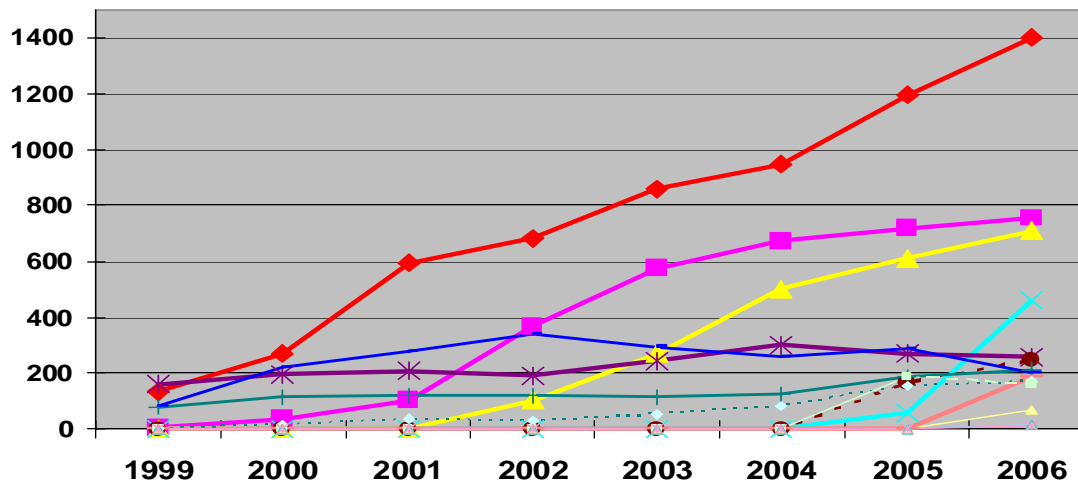
EPIAO – Steady Revenue and Volume Growth

REVENUE (RMB Million)



- ◆ 3SBIO
- KIRIN
- ▲ ROCHE
- ✕ HUABEI
- ✱ CD DIAO
- BJ SIHUAN
- + NJ HUAXIN
- SIBEIKE
- KEHUA
- ◇ SD KX
- SH KL
- ▲ SD AHUA
- ✕ XINPENG
- ✱ SANWEI

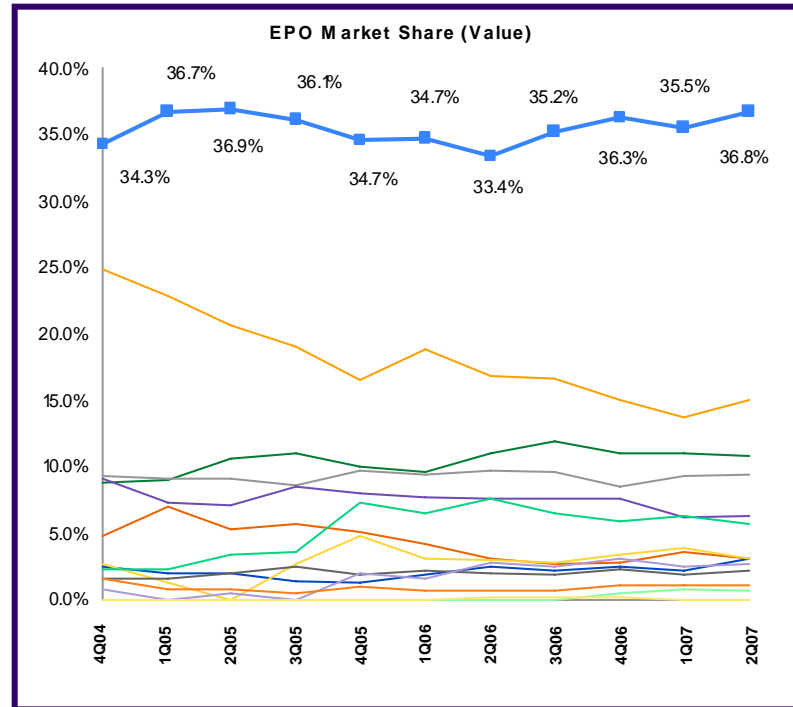
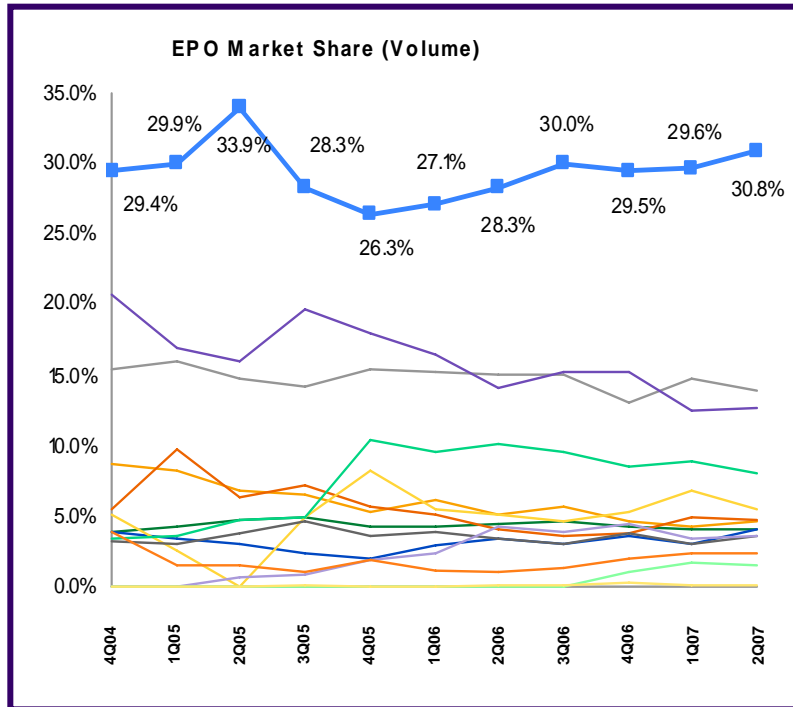
EPO VOLUME (VIALS '000)



* source: IMS Health

EPIAO – Outperforming the Market

EPIAO (益比奥) has been the No. 1 EPO product on the market in both units sold and revenues since 2002



- 3SBio
- Kirin
- Roche
- North China
- Chengdu Diao
- Nanjing Huaxin
- Shandong Kexing
- SciProgen
- Beijing Sihuan
- Shanghai Clone
- Shanghai Ke-hua
- Shandong Ahua
- Shenzhen Xinpeng
- Shanghai Sanwei

益比奥®
EPIAO® (rHuEPO)
重组人红细胞生成素



TPIAO – Fastest Growing, 1st-to-Market TPO



TPIAO (特比澳) is an injectable recombinant human thrombopoietin (rhTPO) product that stimulates production of megakaryocytes to release mature platelets and raising the circulating platelet count

- 1st protein-based therapeutic approved and launched for the treatment of chemotherapy-induced thrombocytopenia, or platelet deficiency, in China
- Phase III results demonstrated higher platelet count in approx. 78% of cancer patients and 85% of ITP patients
- Launched in January 2006
- Rapidly penetrating the market
 - Already represents ~22.3% of sales for the second quarter of 2007
- Phase III clinical trials for ITP indication on going
- Marketing exclusivity period of 5 years through 2010
- 2 patents issued in China covering composition of matter expiring in 2015 and method of manufacturing expiring in 2020

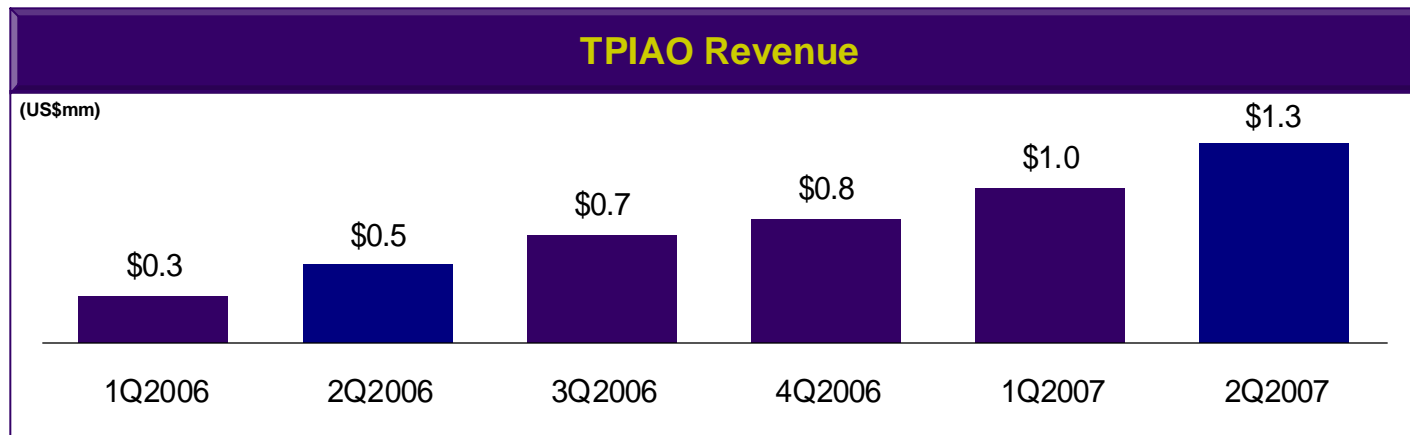


TPIAO—Rapid Growth Quarter over Quarter



2Q07 TPIAO HIGHLIGHTS

- Newest in-house developed product and the fastest growing product in our portfolio
- US\$1.3 million in 2Q07 sales: 263.4% year-over-year increase
- 22.3% of total sales at the end of 2Q07, up from 9.2% for the year-over-year 2Q06
- Phase III trial for treatment of ITP on schedule



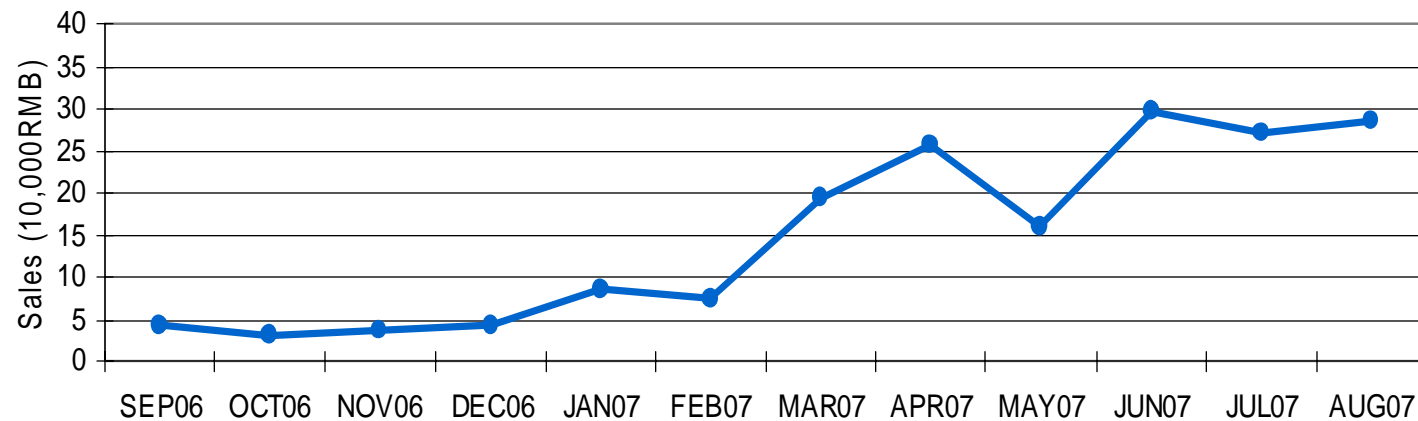


Tietai—Our Recently In-Licensed Product

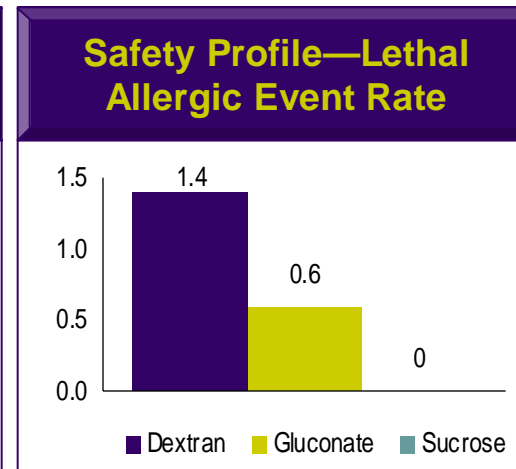
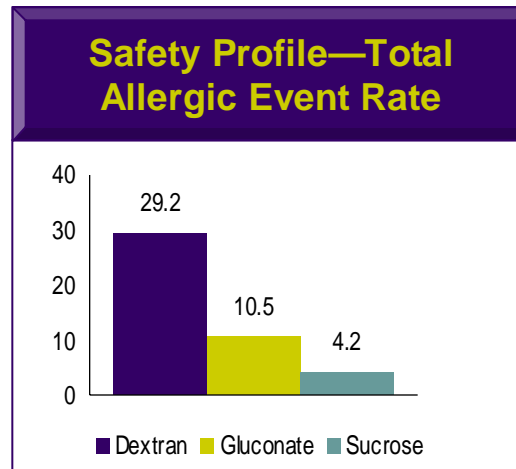
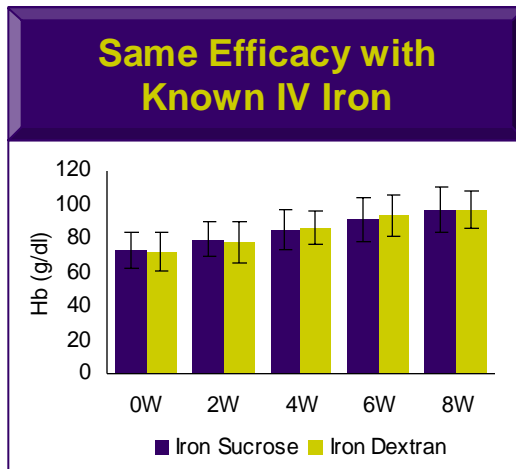
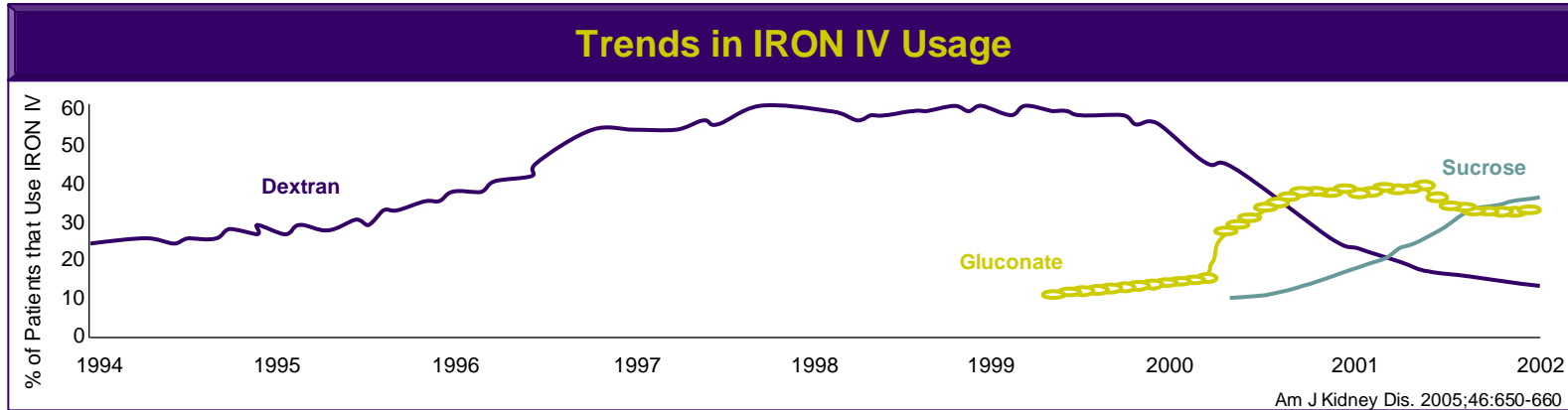
Tietai Iron Sucrose Supplement 铁泰

- Intravenous sucrose solution of a bioavailable form of iron
- Indicated for the treatment of iron deficiency in anemia patients with end-stage renal disease
- Considered to have a superior safety profile compared to other forms of iron supplements
- In-licensed exclusive rights from Shenyang Borui Pharmaceutical Co. Ltd. For 5 years in May 2006
- Highly complementary to the marketing of EPIAO in anemia as these patients often require IV Iron Supplements that occurs from dialysis
- Launched in China in 2005

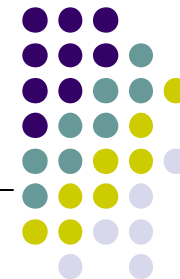
3SBio Iron Sucrose Sales



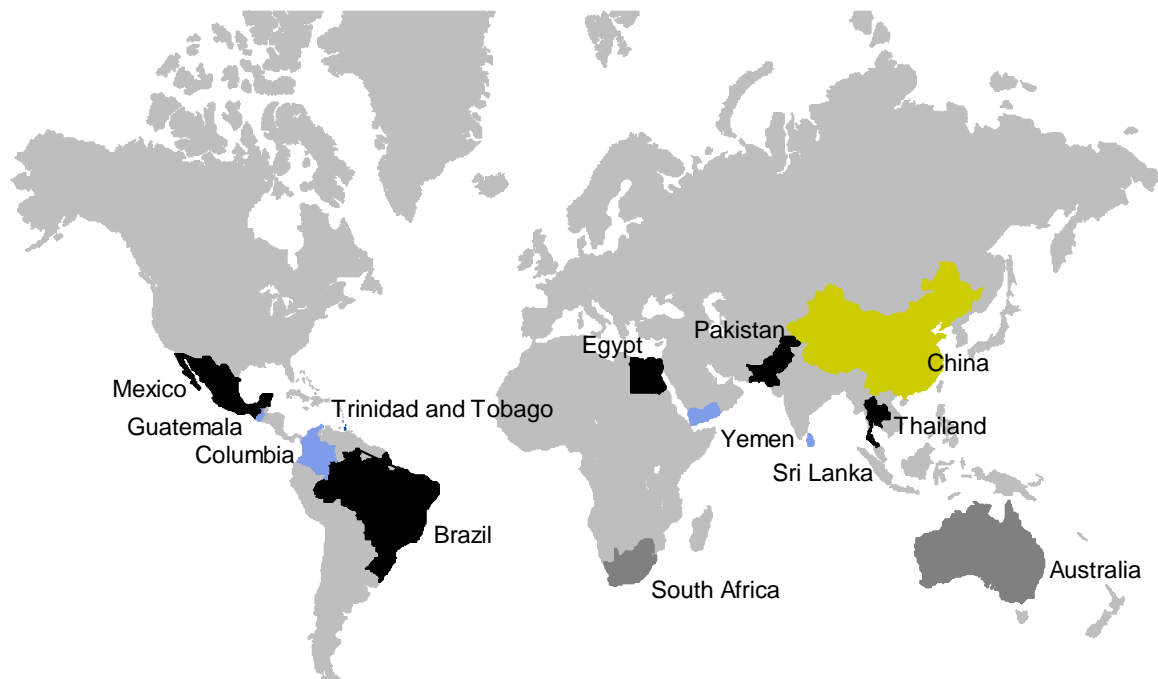
Iron Sucrose Market Trends and Clinical Results



Distributing our Products to Developing Countries all over the World



We currently export EPIAO, Interferon, Inleusin (Interleukin), and Tietai to a number of developing countries



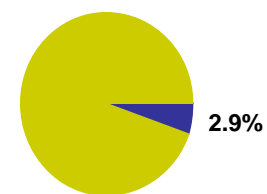
- Domestic Market
- 3SBio Export Countries
- Target Export Countries in Registration
- New Export Licenses 2006

2006 GMP approval for:

- Sri Lanka (March)
- Trinidad & Tobago (July)
- Republic of Yemen (August)
- Guatemala (September)
- Colombia (November).

Export Sales (as of 1H2007)

- Approximately 2.9% of Total Revenues

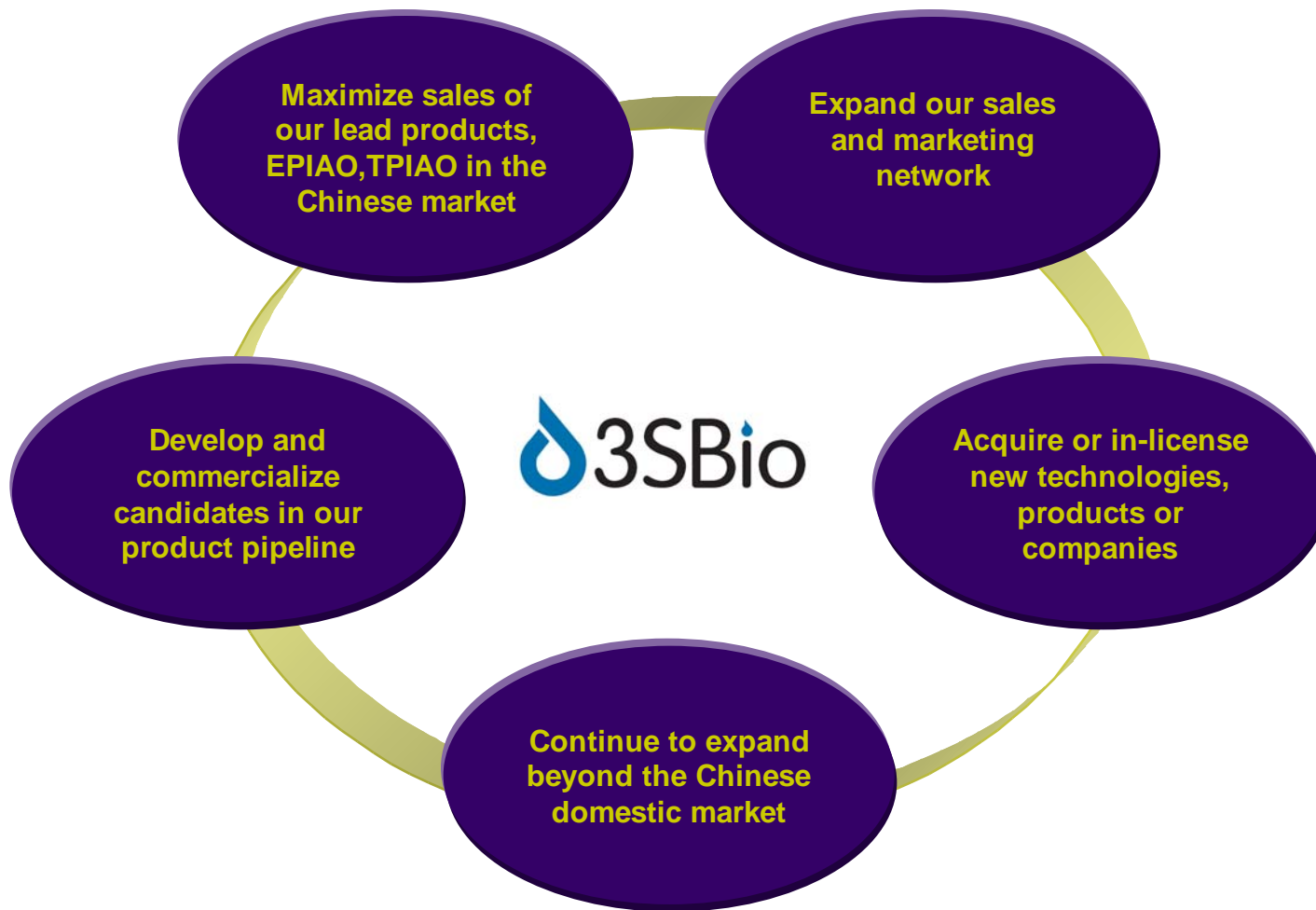


Export Strategy

3SBio Today - Replicate China model in adjacent SE Asia developing nations under penetrated by international players in EPO

Future Opportunities - Focus on biosimilars and open up opportunities in European markets upon receiving EMEA compliance for new and upgraded production facilities

Executing on our focused strategy to drive growth and profitability





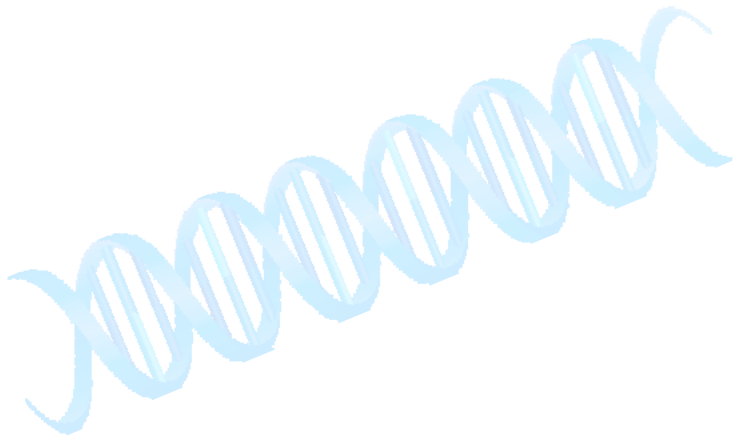
Pursuing M&A Opportunities to Complement Organic Growth



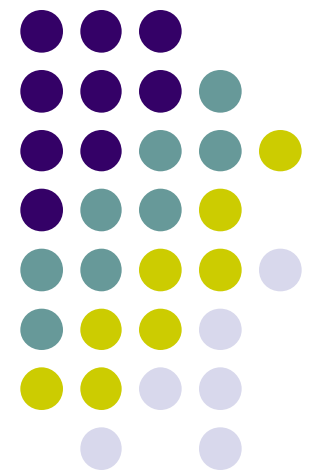
Strategy and Value Driven M&A Approach

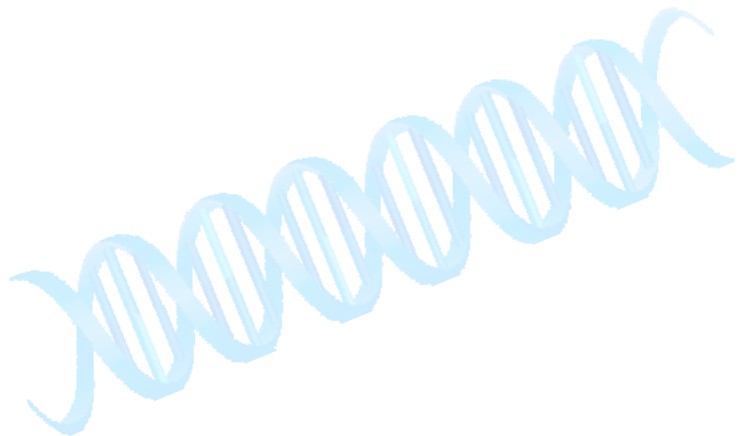
Utilize corporate strategy as “filter” to determine interests in assets, technologies and companies

- Focus on Value Creation
 - Therapeutics that complement our existing product portfolio and sales force expertise
- Seek undervalued assets, technologies and companies
 - Financially sound biotech companies to enhance top and bottom line growth
 - Synergistic products at advance stage of clinical trials to expand product portfolio
 - R&D capabilities that can further enrich our current product pipeline

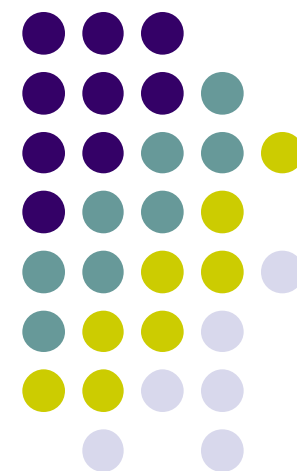


Thank You





Appendix





1H07 Financial Highlights



HIGHLIGHTS				
(in millions)	Six-month period ended			YoY Increase/(Decrease)
	June 30, 2006	June 30, 2007		
	<i>RMB (audited)</i>	<i>RMB (unaudited)</i>	<i>US\$ (unaudited)</i>	%
Net Revenues:	56.9	78.4	10.3	37.8%
Gross profit	51.2	71.5	9.4	39.7%
Total operating expenses	34.0	46.2	6.1	36.0%
Operating income	17.2	25.3	3.3	47.0%
Net income	13.8	39.5	5.2	186.3%
Net income per ADS Basic and diluted (unaudited)	0.97	1.96	0.26	102.1%

2Q07 Financial Highlights – Continued Growth



HIGHLIGHTS				
(in millions)	Three-month period ended			YoY Increase/(Decrease)
	June 30, 2006	June 30, 2007		
	<i>RMB (audited)</i>	<i>RMB (unaudited)</i>	<i>US\$ (unaudited)</i>	%
Net Revenues:	28.9	43.1	5.7	49.2%
Gross profit	25.8	39.1	5.1	51.5%
Total operating expenses	17.7	25.3	3.3	43.2%
Operating income	8.1	13.8	1.8	69.6%
Net income	6.3	23.3	3.1	268.9%
Net income per ADS Basic and diluted (unaudited)	0.44	1.07	0.14	143.2%



Solid and Healthy Balance Sheet



BALANCE SHEET			
(in millions)	June 30		
	2006 <i>(unaudited) RMB</i>	2007 <i>(unaudited) RMB</i>	2007 <i>(unaudited) US\$</i>
Cash	25.3	870.4	114.3
Securities available for sale	-	10.0	1.3
Current Assets	88.5	935.5	122.9
Total Assets	142.5	998.7	131.2
Current Liabilities	39.2	61.9	8.2
Total Liabilities	68.7	66.2	8.7
Minority Interests	0.5	0.6	0.1
Shareholders' Equity	73.3	931.9	122.4
Total Liability and shareholders' Equity	142.5	998.7	131.2



Executing on our Strategy

Since IPO

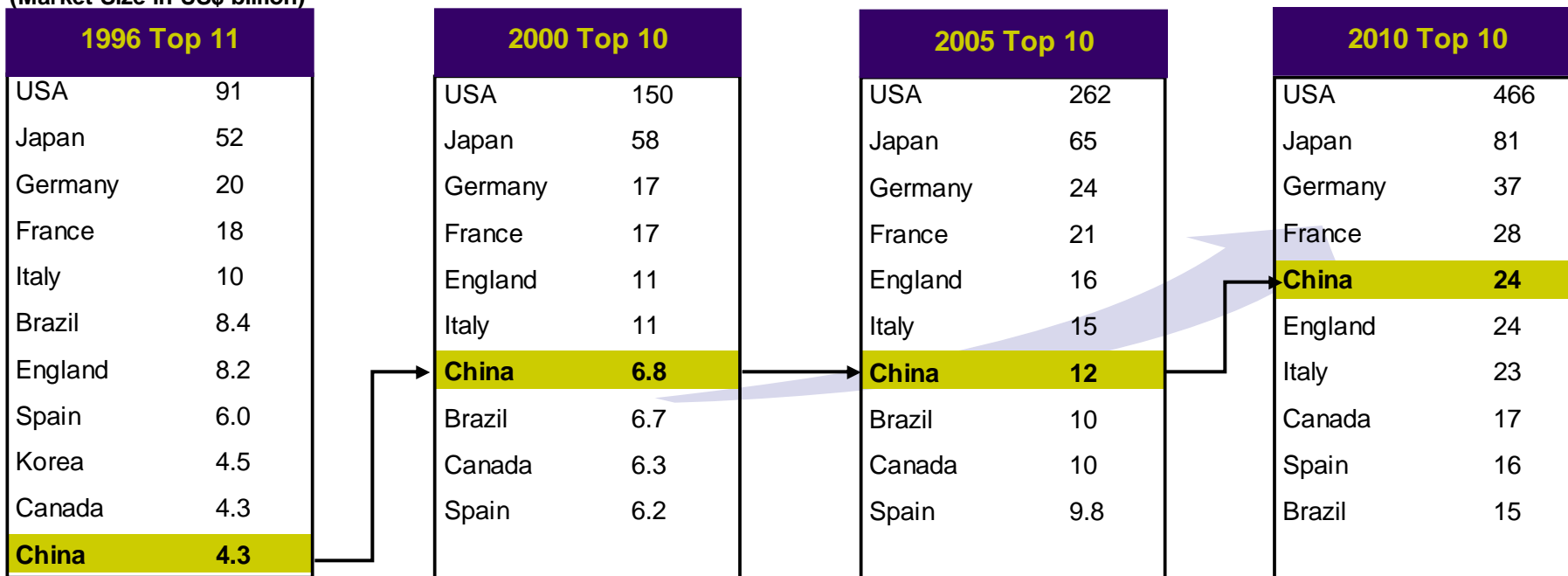
- Grew sales of all core products
- Launched Pre-filled EPIAO Syringe
- Renewed exclusive contract for 19 Beijing Military Hospitals
- Expanded our sales force
- Target additional 121 hospitals by the end of 2007

The Chinese Pharmaceutical Market is Growing at Record Levels



- China is expected to be the World's **fifth largest** pharmaceutical market in five years
- The Chinese Pharmaceutical market **grew** in excess of **15%** from 2000 to 2004*

(Market Size in US\$ billion)



Source: IMS Health

* Source: ISI Emerging Markets

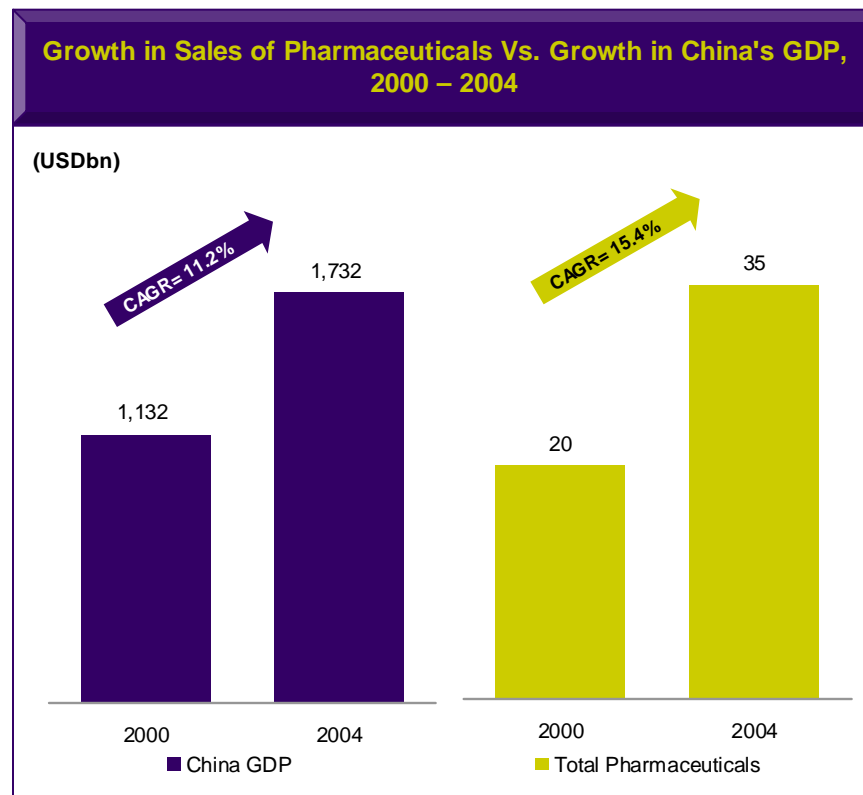
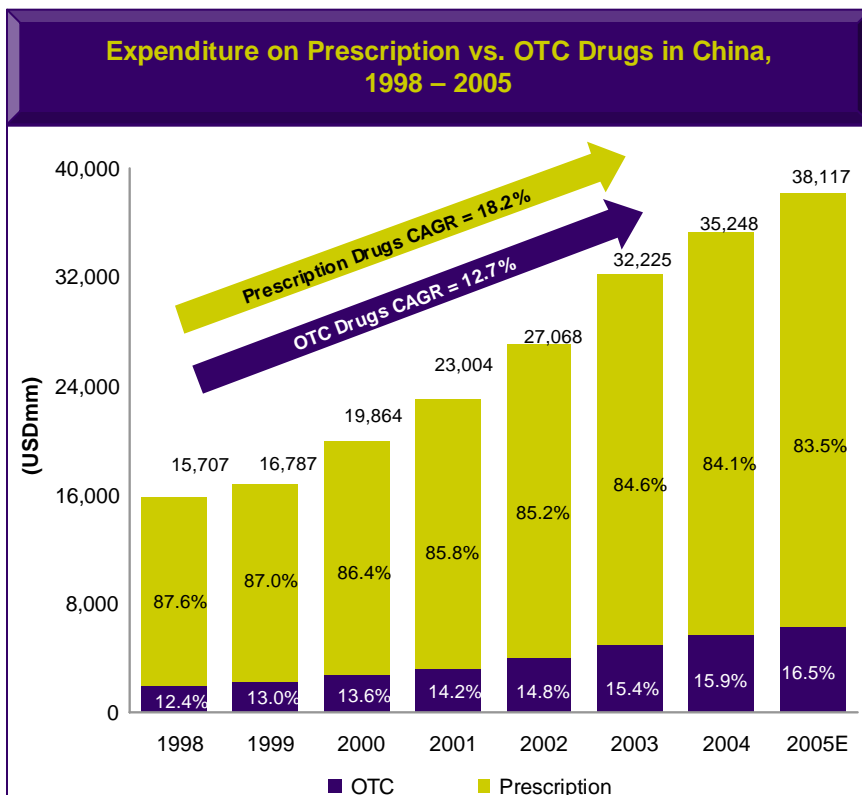
...and 3SBio is well positioned to capitalize on opportunities in China's fast-growing pharmaceutical market



China's Pharmaceutical Industry Growth is Outpacing China's GDP Growth

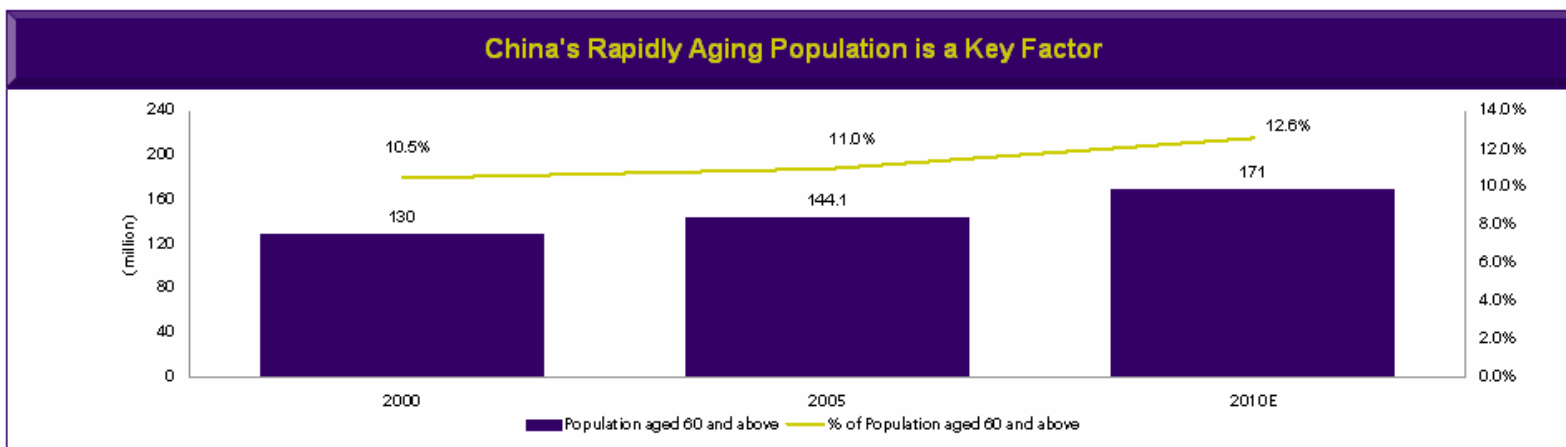


Increasing income and health awareness of the Chinese population have, and are expected to continue to, drive the growth of the pharmaceutical market

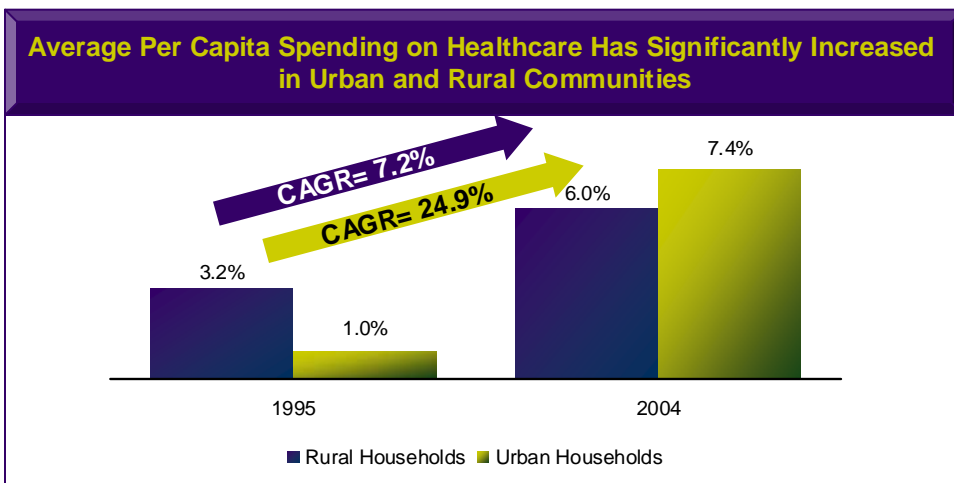


Source: OTC Pharmaceuticals in China: An Overview, ISI Emerging Markets 2005

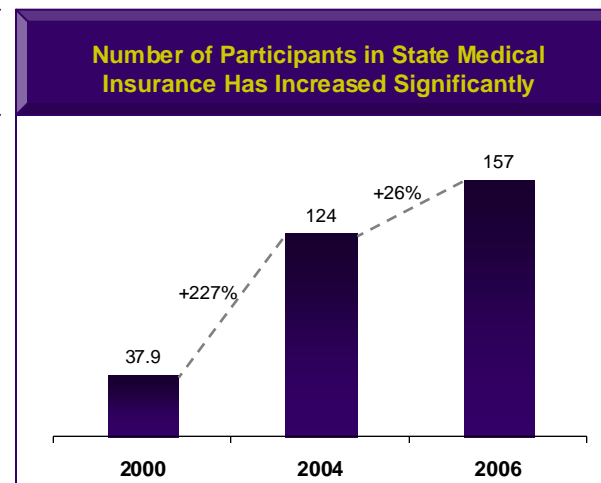
Trends Contributing to the Rapid Growth of the Chinese Pharmaceutical Market



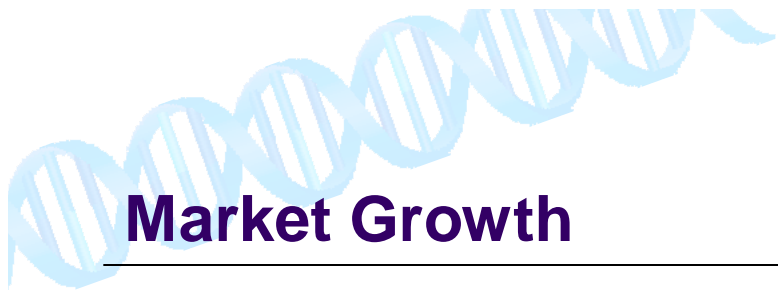
Source: Survey by National Bureau of Statistics in 2000 and 2005, and 2010E is according to the PRC National Population and Family Planning Commission statistics



Source: OTC Pharmaceuticals in China: An Overview, ISI Emerging Markets 2005



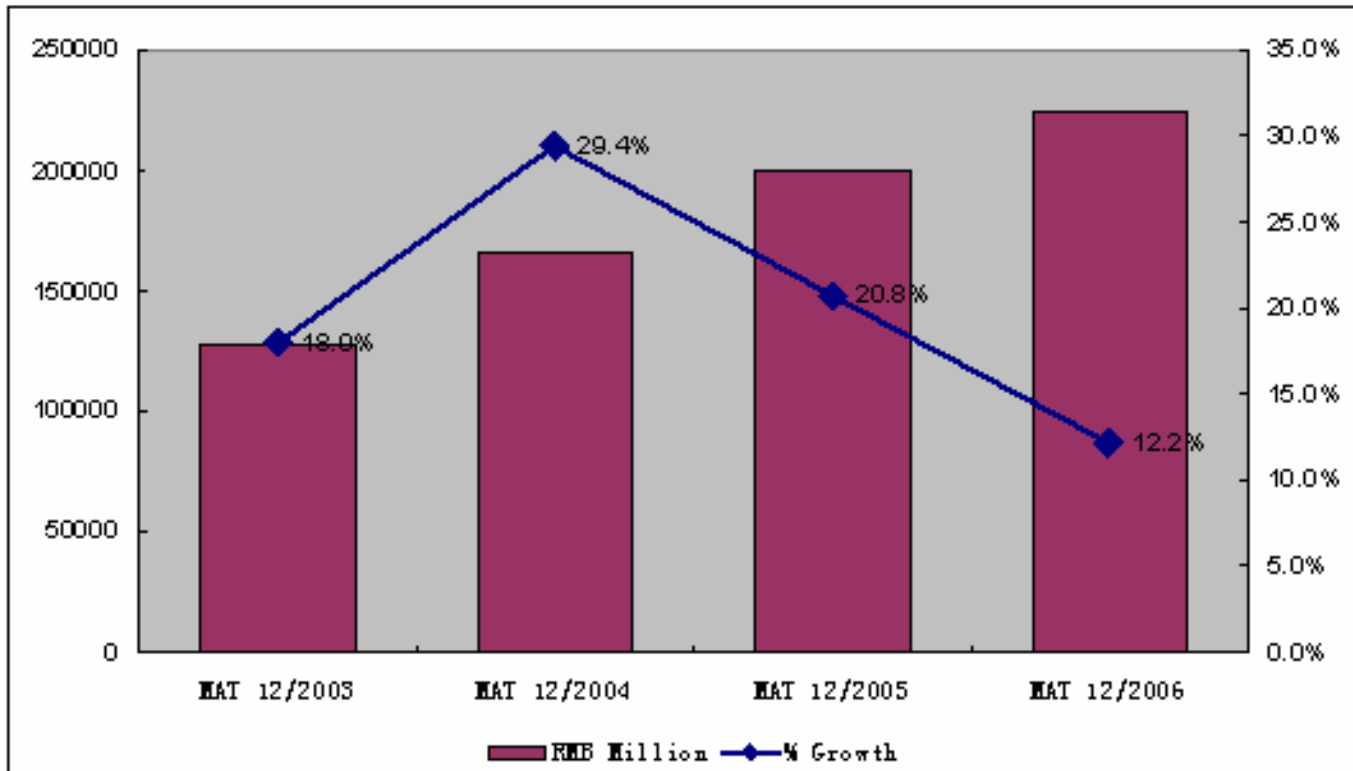
Source: China Labor and Social Insurance Development Statistical Yearbook 2006



Market Growth



Pharmaceutical Market in Hospitals (>=100 beds)



Diverse Portfolio of Marketed Products



Our products target to the oncology and nephrology end markets

Product Name	Indication (s)	Launch Date
EPIAO® (rhEPO) (益比奥®)	Anemia associated with renal failure or chemotherapy, peri-operative blood cell mobilization	1998
TPIAO® (rhTPO) (特比澳®)	Thrombocytopenia	1Q2006
Baolijin® (G-CSF) (保力津®)	Neutropenia	Aug 2006 ¹
Tietai® (Iron Sucrose Supplement) (铁泰®)	Iron-deficiency associated with anemia	Jan 2007
Intefen® (Interferon Alpha-2a, IFN) (因特芬®)	Cancer, Viral infectious diseases	1995
Inleusin® (IL-2) (英路因®)	Renal cell carcinoma, Metastatic melanoma, Tuberculosis	1996

Note:

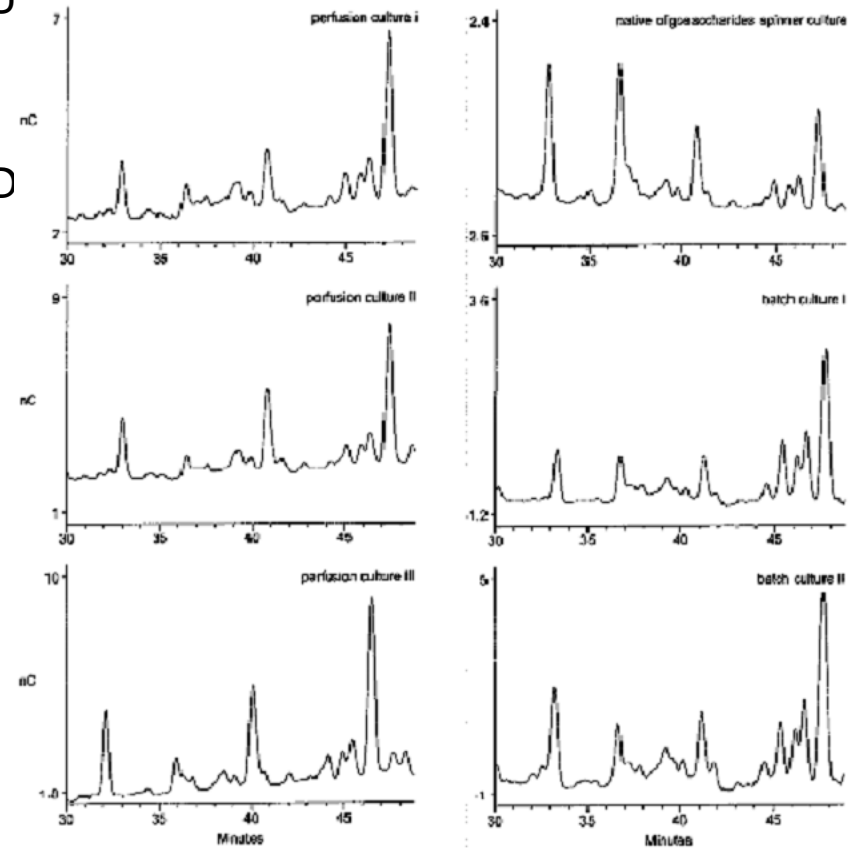
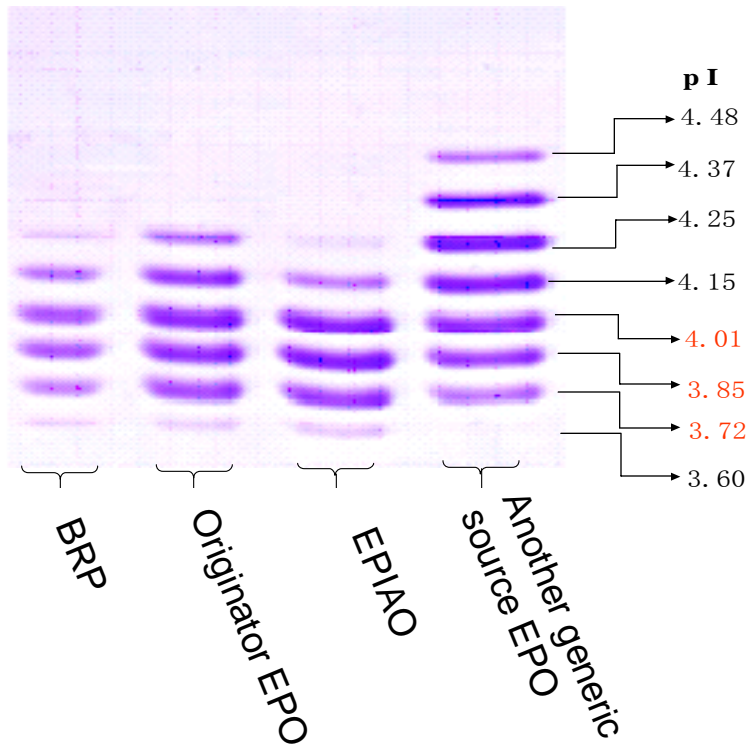
1 Represents the date the product was in-licensed

EPIAO EU 3rd Party Testing Result



The quality of EPIAO is consistent with other branded EPO products

- A reputable preclinical testing center in EU
- CA conform to EU standard
- Potency meet the requirement of EU
- Glycosylation profile done by HPAEC-PAD mapping proved superior structure





High-Dose EPIAO and NuPIAO

High-Dose EPIAO is a 36,000/IU formulation of EPIAO

Key Highlights

- Designed for rapid restoration of hemoglobin to normal levels among cancer patients
- There currently is no dosage form of this kind in China
 - Comparable to standardized dose used globally for anemia
 - Allows for less frequent administration- more convenient for both patient and caregiver
 - Expected to be premium priced
- Plan to complete clinical trials in 2007 and launch in 2008

NuPIAO is the second-generation EPIAO that is designed to have a longer half-life

Key Highlights

- Comparable in structure to Amgen's Aranesp, which is currently the only second-generation EPO product approved by the U.S. Food and Drug Administration
- Preliminary testing of NuPIAO has demonstrated an enhanced half-life comparable to the half-life of darbepoietin alpha
- Extended half-life and increased biologic activity should allow for less frequent administration- more convenient for both patient and caregiver
- Preclinical testing is complete and awaiting SFDA go ahead
- Clinical trials expected to start in 1H08



TPIAO for the Treatment of ITP

ITP is characterized by an immune system malfunction that perceives the body's platelets as foreign and destroys them, potentially resulting in dangerously low platelet counts

Key Highlights

- **New approach to treat ITP by stimulating the TPO receptor, directly increasing platelet production to outpace platelet destruction by the immune system**
- **Multicenter, randomized, placebo-controlled Phase III study in 200 ITP patients**
- **The primary endpoint of this trial is the measurement of platelet counts during the 14 day treatment**
- **Expect to complete Phase III clinical trial by the end of 2007**



NuLeusin– Our 2nd Generation IL-2

NuLeusin, our second-generation IL-2, is a genetically modified form of IL-2 possessing the same properties as naturally occurring IL-2

Key Highlights

- The genetic modification enabled us to produce a high dosage form of IL-2 that has increased stability, superior efficacy, and enhanced tolerability
- Comparable to Chiron's Proleukin, which received U.S. FDA approval for treatment of metastatic renal cell carcinoma in 1992, and for treatment of metastatic melanoma in 1998
- In 2005, we completed an open-label, non-randomized Phase II trial of NuLeusin in 22 patients with metastatic renal cell carcinoma
 - The data demonstrated that NuLeusin effectively reduced the size of the tumors in these patients
 - No serious adverse events reported in this study
- We are currently conducting a multicenter, open-label registrational Phase III clinical study for NuLeusin for the treatment of metastatic melanoma and metastatic renal cell carcinoma
 - Expect to complete Phase III trial in late 2007



Exciting Early-stage Pipeline Candidates

HPV Vaccine

Key Highlights

- Eradication of HPV is a preventative measure against the development of cervical cancer
- In the majority of developing countries, cervical cancer remains the number one cause of cancer-related deaths among women
- The detection rate of HPV in cervical cancer is 98%
- At least 50% of sexually active people will get HPV at some time in their lives
- The annual increase of new Pap smear-positive cases in China is about 10 million
- Our HPV vaccine candidate targets VLPs of HPV-16 and HPV-18

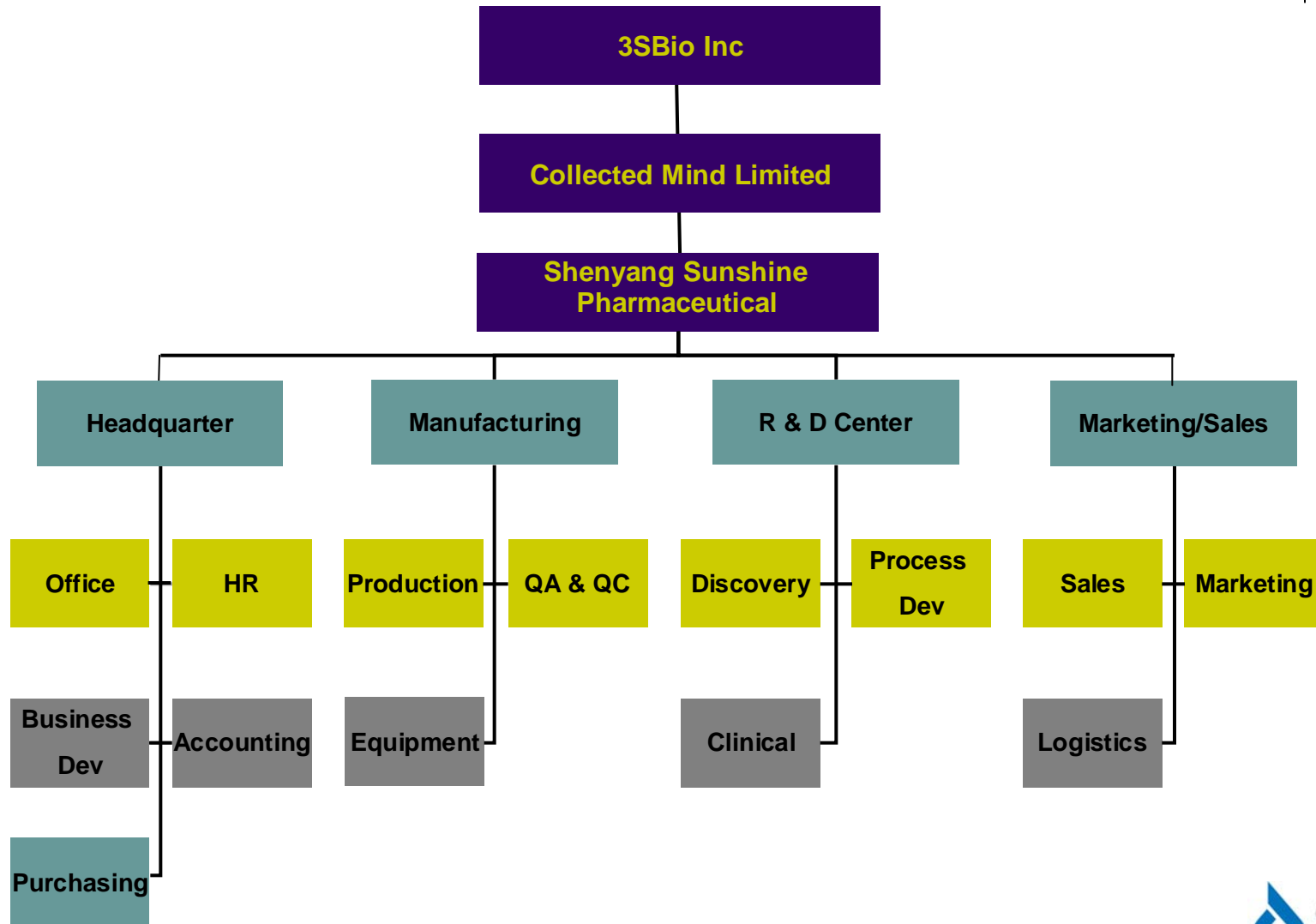
Anti-TNF Humanized mAb

Key Highlights

- Anti-TNF humanized monoclonal antibody designed to bind and deactivate circulating TNF molecules
 - Similar in function to Enbrel, Remicade, and Humira
- We plan to develop our anti-TNF mAb candidate in collaboration with Epitomics, Inc.
 - US-based biotechnology company that is recognized for its proprietary high-affinity rabbit monoclonal antibody humanization technology



Organization Structure





3SBio Patents



Title	Application No.	Application Date	Status	Patent No.
Human thrombopoietin	95110172.2	4/14/1995	Issued	ZL 95110172.2
Process for preparing recombinant human thrombopoietin preparation	00109612.5	6/19/2000	Issued	ZL 00109612.5
Method for improving stability of polypeptide in body and its application	01128011.5	8/7/2001	Issued	ZL 01128011.5
Recombinant alpha interferon gelatin injection	02132574.X	7/11/2002	Issued	ZL 02132574.X
Stable erythropoietin of recombined human red blood cell	03100653.1	1/20/2003	Issued	ZL 03100653.1
Production of a interleukin mimetics	20610046222.2	3/31/2006	Filed	



3SBio Positioned to Benefit from Favorable Government Regulation Trends



- Increased government spending
- Price cuts will be less frequent in the future
- New SFDA to become more cautious on approval
- Anti-corruption will be more focused on the distribution channels
- New healthcare system
- Common Name System
- Pharmacy trusteeship
- Designated drug manufacturing



Overview of the Chinese Reimbursement System



- All employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premiums are jointly contributed by the employers and employees*
- Drugs that are covered by the basic insurance program are limited to those listed in the Insurance Catalogue, including:
 - Pharmaceutical products listed in the 2005 version of the PRC Pharmacopoeia
 - Pharmaceutical products approved by the government to be in compliance with national standards, and
 - Imported pharmaceutical products approved by the government
- Insurance Catalogue consists of two parts, Part A and Part B:
 - Patients purchasing drugs included in Part A are entitled to reimbursement of the entire amount of purchase costs
 - Patients purchasing drugs included in Part B are required to pay a deductible and obtain reimbursement for the remainder of the purchase costs. The amount of deductible differs from region to region in China

* Pursuant to the Decision of the State Council on the Establishment of Basic Medical Insurance System for Urban Employees issued by the State Council on December 14, 1998



Price Control in Chinese Healthcare Industry



- Prices of pharmaceutical products are either determined by the government or by market conditions
- The government sets a price ceiling for the retail prices of products based on:
 - the average production cost of the pharmaceutical manufacturers
 - the market demand and supply of such products while allowing some room for adjustment from time to time
- Pharmaceutical products included in the Insurance Catalogue or those which tend to have a monopoly nature, are subject to overall price review to:
 - reduce the retail price of certain overpriced pharmaceutical products, or to
 - increase the retail price of certain underpriced pharmaceutical products with demand in clinical use but the manufacturers have little incentive to produce due to their low retail price levels
 - In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for certain Chinese medicine products
- If a particular pharmaceutical manufacturer has an advantage over efficacy, safety, treatment cycle and treatment costs of its product, such pharmaceutical manufacturer may apply for an approval for exemption from price control, subject to a public hearing held by the government
- The State Development and Reform Commission issued the Notice to regulate the maximum retail price as well as the maximum post factory price of certain pharmaceutical products intended to treat vitamin or mineral deficient diseases



Overview of Chinese Administrative Protection Laws



- The 1999 Regulations provides a six to twelve year administrative protection period for different categories of new drugs
 - During the protection period of a new drug manufactured by a specific pharmaceutical company, other enterprises or individuals are prohibited from manufacturing a similar drug or expanding the label of any existing similar drug to include the same indication
- The 1999 Regulations were replaced by the 2002 Regulations, which was later revised in February 2005. However, any drug granted a protection period prior to September 2002 will still enjoy the protection period until its expiry
- The 2002 Regulations provide an administrative monitoring period of up to five years for new drugs approved to be manufactured, to continually monitor the safety of those new drugs
 - During the monitoring period of a new drug, the SFDA will not approve any other enterprises' application to manufacture or import a similar new drug
 - Only exception: SFDA will continue to handle any application if, prior to the commencement of the monitoring period, the SFDA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the SFDA may approve such applicant to manufacture or import the similar new drug during the remaining of the monitoring period



Summary of SFDA Code 28 – Government Regulation on PRC Drug Registration



- The applicant must provide adequate and reliable data to prove that the drug safety, effectiveness and quality control, as well as full responsibility for the validity of the information
- The required pre-clinical drug research, for the purpose of drug registration, should include drug synthesis, extraction methods, chemical properties and purity, dosage selection, prescription screening, production technology, test methodology, quality indicators, stability, pharmacology, toxicology, and animal pharmacokinetic studies
- There are 4 phases of clinical trial before applying for new drug
 - Phase I: preliminary clinical pharmacology and human safety evaluation.
 - Phase II: preliminary evaluation of effectiveness of the treatment of target patients and its safety
 - Phase III: treatment corroboration stage in order to further validate effectiveness of the treatment of the target patients and its safety, as well as the assessment of benefits versus risks
 - Phase IV: after the new drug launched into the market, investigation of the widespread use of the drug in terms of its efficacy and adverse reactions
- Clinical trial cases should be consistent with respect to the purpose of the clinical trials and relevant statistical assessment, and shall not be less than the respective minimum requirement
- After completing clinical trials, applicants should submit final report of clinical trials, statistical analysis and relevant database to the State Food and Drug Administration (SFDA)
- In order to protect public health, the SFDA has the right to establish monitoring period (maximum 5 years) for new drug under production. During this monitoring period, the SFDA will not approve other enterprise to produce, to change dosage, or to import similar drugs

* Pursuant to the Drug Registration Procedure promulgated by SFDA to be effective starting October 1, 2007



Summary of SFDA Code 28 – Government Regulation on PRC Drug Registration (continue)



- Pharmaceutical enterprises who has gained the new drug production approval but did not initiate the proposed production after 2 years from the date of the approval, the SFDA can approve other enterprises to produce the new drug and re-establish the appropriate monitoring period for the new drug
- At the start of the monitoring period for the new drug, if SFDA has already approved the pre-clinical trials of similar drugs for other applicants, these applicants can continue its drug registration process and obtain the necessary approvals for production or importing. Then, SFDA will monitor both the drugs under production
- At the start of the monitoring period for the new drug, SFDA will not accept applications for similar drugs and will return the applications which have not gained pre-clinical trial approval for the similar drugs. Only after the completion of the monitoring period, other applicants of similar drugs are allowed to apply.
- The drug registration cards - the “imported drug registration card”, or the “pharmaceutical products registered card”, issued by SFDA, is valid for a period of five years. The applicants who want to continue production or imports, should re-apply for the registration 6 months before the expiration date.
- Drug testing time for registration purpose is in accordance with the following provisions:
 - Drug sample testing ~30 days
 - Drug sample testing with simultaneous standard review ~60 days
 - Special drugs and vaccines product samples testing ~60 days
 - Special drugs and vaccines product samples testing with simultaneous standard review ~90 days

* Pursuant to the Drug Registration Procedure promulgated by SFDA to be effective starting October 1, 2007



Summary of SFDA Code 28 – Government Regulation on PRC Drug Registration (continue)



- Drug technical review time for registration purpose is in accordance with the following provisions:
 - Drug under clinical trials ~90 days
 - Drug under clinical trials with approved special procedure ~80 days
 - Drug under production ~150 days
 - Drug under production with approved special procedure ~120 days
 - Change of dosage or generics application for listed drug on the market ~160 days

- * Pursuant to the Drug Registration Procedure promulgated by SFDA to be effective starting October 1, 2007



Clinical Trial Overview (China vs U.S.)

	U.S.	China
Characterization of Cell Bank	Karyology and Tumorigenicity NOT Required	Karyology and Tumorigenicity Required
Testing for IND/BLA	Not Required	1-3 batches for IND 3 batches for BLA
Pre-clinical Studies	6-9 months for Multi-Dose Toxicology Toxicokinetics Required	1-9 months for Multi-Dose Toxicology Toxicokinetics NOT Required Non-human primate are used in most of cases
Clinical trials	Phase I 20-80 subjects Phase II 100-300 subjects Phase III 1000-3000 subjects	Phase I 20-30 subjects Phase II 100 subjects Phase III 300 subjects