



**David Segarnick Ph.D.**  
Managing Director

## KEEPING THE FAITH?

David Segarnick, Ph.D., the head of BERYL Pharma360, heralds an exciting start to the year for Chinese Pharmaceutical and Biotech firms. Dr. Segarnick explains his recent observations and strategic implications and growth drivers for this increasingly important sector.

## CHINA PHARMA & BIOTECH OUTLOOK FOR 2012

### KEY FINDINGS

- Widespread overuse of antibiotics across China has led to multi-drug resistance and increased morbidity and mortality. Due to the implementation of the antibiotic restriction policy, antibiotic sector growth decelerated to 16% in 3Q11, down from 18% in 1H11 and 22% for 2010, but is expected to accelerate into 2012.
- Multinational pharmaceutical companies (Pfizer, Abbot, Bristol-Myers Squibb, Glaxo, Roche, Lilly, Bayer, Astellas, Eisai, Novartis, Sanofi, AstraZeneca, Takeda, Daiichi Sankyo, Johnson & Johnson, Merck) recently obtained SFDA approvals that accounted for 33% of total China pharmaceutical industry sales concentrated in diabetes, oncology and cardiovascular drugs, eating into the domestic market share of Chinese companies (see the table below).

### SFDA Regulatory Approval of MNC Drugs (2011 to present)

Brand Name	Company	Product Name (chemical name)	License number	Approval date	Therapeutic area
Zyvox	Pfizer	Linezolid Injection	H20110312	07/18/11	Antibiotics
NORVIR	Abbott	Ritonavir Tablets	H20110305	07/18/11	Infectious
Duspatalin	Abbott	Mebeverine Hydrochloride Tablets	H20110293	07/14/11	Digestive
Femoston	Abbott	Complex Packing Estradiol Tablets/Estradiol and Dydrogesterone Tablets	H20110208	04/26/11	Reproductive
Onglyza	BMS	Saxagliptin Tablets	J20110029	07/18/11	Diabetes
SPRYCEL	BMS	Dasatinib Tablets	H20110429	09/07/11	Oncology
Avodart	GSK	Dutasteride Soft Capsules	H20110205	04/11/11	Urology
Ventolin Nebules	GSK	Salbutamol Sulfate inhalation solution	H20110457	10/21/11	Respiratory
Avandamet	GSK	Metformin Hydrochloride and Rosiglitazone Maleate Tablets	H20110336	07/17/11	Diabetes
Herceptin	Roche	Trastuzumab Injection	J20110020	03/30/11	Oncology
Humalog Mix 50	Eli Lilly	Mixed Protamine Zinc Recombinant Human Insulin Lispro Injection (50R)	S20110068	10/12/11	Diabetes
Cymbalta	Eli Lilly	Duloxetine Hydrochloride Enteric Capsules	H20110320	07/19/11	Neural
Humalog Mix25	Eli Lilly	Mixed Protamine Zinc Recombinant Human Insulin Lispro Injection (25R)	J20110019	03/30/11	Diabetes
FORSTEO	Eli Lilly	Teriparatide Injection	S20110021	03/04/11	Osteoporosis
Ca-D-Vita	Bayer	Calcium Carbonate and Vitamin D Effervescent Tablets	H20110460	10/24/11	Vitamin
Bayaspirin	Bayer	Aspirin Chewable Tablets	H20110419	09/02/11	Others
Cefzon	Astellas	Cefdinir Capsules	H20110330	07/17/11	Antibiotics
Aricept	Eisai	Donepezil Hydrochloride Orally Disintegrating Tablets	H20110453	10/21/11	Neural
Galvus	Novartis	Vildagliptin Tablets	H20110359	08/15/11	Diabetes

Source: SFDA

### **KEY FINDINGS, cont.:**

- Consensus opinion is that the greatest threat in 2012 and beyond for Chinese pharmaceutical companies is downward pressure on domestic as well as international growth caused by the fragmented nature of the Chinese healthcare / pharmaceutical market and increasing government price controls and regulations. Companies including Mindray, Weigao, Sinopharm, Shanghai, Shineway, SinoBiopharm, United Labs, Sihuan account for approximately two-thirds of all sales in China. This downward pressure on domestic and international growth outpaces margin erosion by a factor of two (Deutsche Bank survey, Dec. 2011). As a result, half of the top 100 public Chinese healthcare stocks lost their value in 2011.
- Chinese public pharmaceutical firms as a group have performed poorly in 2011 and this year. There is significant market uncertainty going forward regarding government policy trends. Drug price controls are likely to continue via NDRC pricing reform. The provincial tender process and cost control, through changes in insurance reimbursement have created additional pressures on the sector.

### **STRATEGIC IMPLICATIONS AND GROWTH DRIVERS**

- The best opportunity for growth for Chinese pharmaceutical companies is to expand its traditional medicine (herbs) offerings to the West. These agents have proved safe and effective for a millennium and could move quickly into FDA and EMEA review.
- Additionally, China has a number of new pre-clinical and clinical stage compounds targeted to treatment-resistant diseases as a result of a long and vast commitment to science education at the college and graduate school level. This has facilitated the development and commercialization of late stage novel pharmaceutical products originating in China. These novel agents need to be commercialized in Europe and the US as well.
- Perhaps the greatest obstacle in this regard has been a lack of understanding or experience in western healthcare product development and marketing as well as lack of awareness of competitive landscape in the EEU and the US.

## **THE LEADER IN MEDICAL COMMUNICATION AND STRATEGY**

**BERYL China Pharma360 is uniquely suited to provide Chinese pharmaceutical companies interested in expansion into western markets with the following services to support these growth opportunities:**

- Pharmaceutical/Biotech pipeline scoping, branding, therapeutic landscape and competitive analysis.
- Product lifecycle planning to increase domestic and international sales.
- Scientific platform development to help create pre-launch and launch core communications messaging across multiple internal and external groups.
- "Best practices" evaluation and guidance for product planning and for companies interested in international product introductions and partnering.
- Analysis and lessons learned in the integration of traditional herbal medicine in healthcare and into modern pharmaceutical product development.
- Data surveillance and onsite coverage at major international medical congresses used to provide therapeutic landscape and competitive data analysis.
- In addition to providing expertise in Medical Communication and Strategy, we provide consulting services with regards to selection of specialists in the areas of legal/regulatory, intellectual property, product branding and corporate finance.
- **Current and past clients:** Pfizer, Novartis, GSK, Amgen, Janssen, Sanofi, Merck, Astellas, Cephalon.

### **ABOUT BERYL PHARMA360**

**Beryl's independent hedge fund research and advisory services are natural adjuncts to Beryl Pharma360 pre-marketing analytics. Pharma360 provides healthcare executives with actionable competitive landscape analysis to support "go/no-go" decisions prior to seeking international partnerships for new product introductions in the US and Europe. We use state-of-the-art data collection and analysis including therapeutic landscape and competitive product intelligence, major congress data surveillance, best practices evaluation and scientific platform key message development. Pharma360 consulting services are a cost-effective and proven method to evaluate risk/benefit prior to committing to international product development and/or making partnering decisions.**