

Overcoming Challenges to Maximise Potential

Executive Summary

We attended the Pharma Summit 2009 held by the Confederation of Indian Industry (CII) in Mumbai. The Summit focused on identifying, understanding and overcoming the key execution challenges being faced by the Indian Pharma companies as well as realising the untapped potential of the various business segments in the Pharma Sector. The forum was also used to discuss the various strategies that the Indian Pharmacos could adopt to tackle and overcome the challenges.

■ **Scaling new orbits:** The Indian Pharmaceutical Sector has demonstrated the potential to emerge as one of the world's leading and fastest growing markets and formed an integral part of drug development, manufacturing and supply chain. India has proved its credentials not only by making its mark as a supplier of high-quality low-cost generic drugs, but also by consistently moving up the value chain to successfully foray into more challenging segments such as drug discovery and development and biopharmaceutical. In fact, India's has already emerged as the preferred hub in the global pharmaceutical market.

■ **Focusing on challenges to realise true potential:** The Summit focused on identifying and understanding the key execution challenges being faced by the Indian Pharmacos and discussed ways in which to realise their potential across the following business segments:

● **Global Generics:** The global generics are expected to post a CAGR of around 10.5% over CY2007-12E, outperforming the overall Pharma market CAGR of 5.5% in the mentioned period. Generic sales, particularly to foreign markets, are expected to remain the largest business segment for the Indian pharmacos. However, the pharmacos have been facing hurdles such as managing multiple regulatory systems, patent exclusivities, extensions and expiries while catering to the foreign markets. In fact, complexities have only risen with the number of foreign markets being served increasing in number. Thus, it is imperative that the players build strong competencies across the value chain and constantly re-align their business focus and costs according to changing market conditions to succeed in the global generic markets.

● **Domestic Formulations:** The Indian Domestic Formulation industry registered a CAGR of 14% during FY2003-08 from around US \$3.9bn in FY2003 to US \$7.7bn in FY2008 outpacing the Global Pharma Industry growth rate of 7%. Going ahead, the Indian Domestic Formulation market is expected to report robust CAGR of 12.2% to US \$13.7bn over FY2008-13E. By CY2015, India is expected to rank among the Top-10 global Pharmaceutical markets. However, the Indian companies are grappling with the issues of having complex distribution model and diverse market. Hence, to ensure a profitable business model across the diversified domestic market, companies need to ensure optimal reach.

● **Contract Research and Manufacturing Services (CRAMS):** Global Innovators are under pressure due to a number of factors including growing patent expiries of major blockbuster drugs, price restrictions and a slowdown in new product approvals and launches. To add to these pressures, there has been a decline in R&D productivity resulting in further deceleration in bringing new blockbuster drugs to the market leading to a difficulty in maintaining historic growth rates and revenue levels. Managing quality and delivery timeliness is identified as the key challenge faced by Indian companies. For Indian companies it is important to focus on developing sustainable relationships with the clients. This can be achieved by winning the confidence of the client by successfully executing big-ticket contracts.

● **Clinical Research Services:** India is amongst the preferred destinations for foreign companies struggling to cope with the pressures of rising R&D costs, declining productivity and approval of new product launches. However, the motivation to outsource drug development

Sarabjit Kour Nangra

Tel: 022 - 4040 3800 Ext: 343

E-mail: sarabjit@angeltrade.com

Sushant Dalmia

Tel: 022 - 4040 3800 Ext: 320

E-mail: sushant.dalmia@angeltrade.com

to India goes well beyond the cost consideration. The Indian Clinical Research Services market is still at a nascent stage. While the Indian Clinical Research Organisations (CROs) are working on building scale, they appear to be facing a dilemma regarding their expansion plans. The Indian CROs need to develop a global footprint and a broader range of service offerings, which could offer tremendous advantage to them.

- **New Chemical Entity (NCE) discovery and development:** Indian companies have preferred to stay away from this business segment, which entails substantial investment in terms of money, time and other resources coupled with very high risk of failure. The Indian companies also lack experience in developing their own molecules, especially the experience to take the molecules through the advanced stages of development. The Collaborative Research model can mitigate the risks of failure and bring in the required investment.

- **Biopharmaceuticals:** The Indian Biotechnology Industry though small, the players have managed to make their presence felt in the global markets. Based on India's strong value proposition, the country's potential to emerge as a leading player has been well accepted globally. However, given the high regulatory standards, overall penetration into highly regulated markets has been challenging. Biotechnology being a relatively new industry with a large number of start-ups, it is important that the government, educational institutions and financial investors collaborate closely with the industry players to tackle the afore-mentioned challenges and build a strong base. It may be noted here that the industry posted a CAGR of 40% during FY2003-08.

Our Take: Going ahead, the US will continue to be the largest market for generics. Indian companies are looking at products with high technological barriers and limited competition to generate steady cash-flows. On the domestic front, we expect companies with higher proportion of Chronic and Lifestyle product sales, better supply chain management and higher Revenue per sales force to lead the pack. We continue to favour the CRAMS Segment. Currently, however, the Segment is witnessing near-term hiccups by way of inventory de-stocking at the Innovator's end, which is expected to last for few more quarters. Over the longer term, we expect this space to witness secular growth. CROs with presence in multiple geographies and providing a full range of services will be the key differentiators. We expect Out-licensing and Collaborative Research to be adopted by the Indian companies engaged in NCE Research given the substantial financial requirement and low success rate. In the Biopharma space, though EU, Japan and other developed markets have approved legislation for biosimilars, regulatory clarity in the US market would be a major catalyst for further investments in the Segment.

Our Picks: Cadila Healthcare, Lupin, Piramal Healthcare and Ipca Labs.

Exhibit 1 : Valuation Snapshot

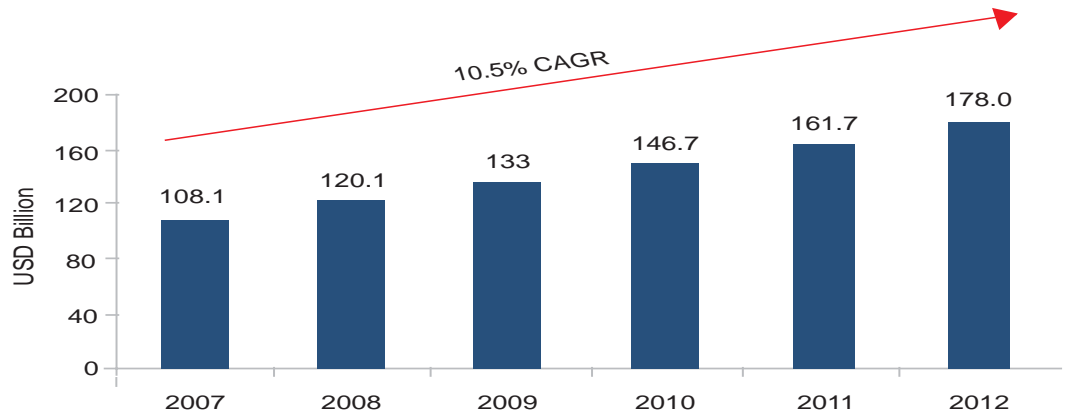
Companies	Reco	CMP (Rs)	Target Price (Rs)	Upside (%)	Mcap (Rs cr)	PE (x)		EV/Sales (x)		EV/EBITDA (x)	
						FY10E	FY11E	FY10E	FY11E	FY10E	FY11E
Alembic	Reduce	52	47	(10)	710	11.5	8.9	0.9	0.8	7.2	5.7
Aventis*	Reduce	1,540	1,363	(11)	3,547	20.8	18.1	1.3	1.1	6.3	5.4
Cadila Healthcare	Accumulate	519	541	4	7,080	16.0	14.4	1.4	1.2	7.2	6.5
Cipla	Neutral	280	-	-	21,743	20.6	18.8	4.1	3.6	21.6	20.8
DRL	Neutral	988	-	-	16,673	24.1	18.4	2.4	2.1	14.1	11.2
GSK Pharma*	Reduce	1,557	1,386	(11)	13,186	25.1	22.5	4.9	4.4	14.0	12.9
Indoco Remedies	Accumulate	238	269	13	293	5.9	5.3	0.8	0.6	4.4	3.7
Ipca Labs	Accumulate	800	855	7	1,998	11.7	9.4	1.6	1.4	8.1	6.7
Lupin	Accumulate	1,137	1,290	13	9,796	14.9	13.2	2.3	2.0	11.2	9.9
Orchid Chemicals	Neutral	181	-	-	1,278	18.3	8.3	2.0	1.7	7.4	6.4
Piramal Healthcare	Accumulate	383	397	4	7,997	17.0	14.5	2.4	2.1	11.4	9.9
Ranbaxy*	Sell	403	251	(38)	16,942	-	98.6	2.5	2.3	245.0	58.1
Sun Pharma	Sell	1,399	1,181	(16)	28,982	22.5	19.0	6.1	5.2	19.2	15.6

Source: Company, Angel Research. Note: * Y/E December

Global Generics

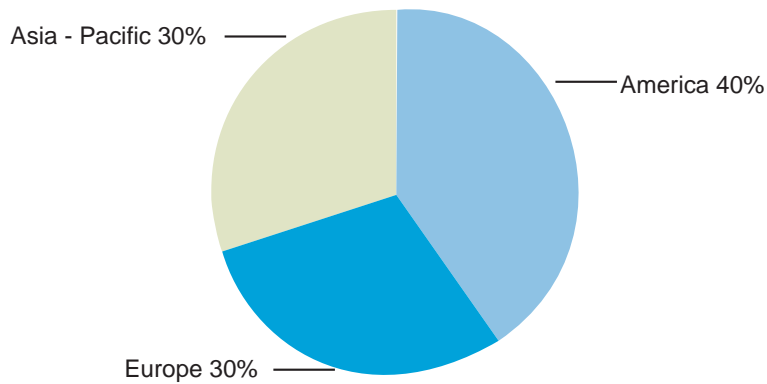
The global generics market is expected to register a CAGR of around 10.5% over CY2007-12E, outperforming the estimated industry CAGR of around 5.5% in the mentioned period.

Exhibit 2: Global Generics - Growth Trend



Source: CII-KPMG Pharma Summit 2009

Exhibit 3: Global Generics Market Size



Source: CII-KPMG Pharma Summit 2009

India has emerged a prominent supplier of high quality generic drugs globally. This success can be attributed to the recognition of process patents over the last three decades, which played a pivotal role in the development of the country's reverse engineering and chemical synthesis skills. The strategic alliances between Innovators and Indian drug makers well signifies this success.

Exhibit 4: Recent alliances with Indian Companies

Alliance	Rationale
Pfizer-Aurobindo	The alliance is expected to strengthen Pfizer's generic product portfolio in the regulated markets and reduce dependence on brand products.
Pfizer - Claris Lifesciences	Pfizer is expected to sell Claris' injectable products under its own brand name.
GSK - Dr Reddy's	The partnership is expected to strengthen GSK's portfolio in the emerging markets as it would have access to DRL's 100 products.

Source: CII-KPMG Pharma Summit 2009

Key Challenges

- **Managing different regulatory needs** : Every market has its own regulatory authority and drug approval mechanism. Managing multiple regulatory systems, patent exclusivities, extensions and expiries is challenging and this complexity increases with the number of foreign markets served.
- **Slowdown in product approvals**: Over the last few quarters there has been a slowdown in the approvals by the US FDA / EMEA. One commonly cited reason is that the US FDA office is overburdened and is facing a shortage of manpower. It is also believed that the US FDA / EMEA, already considered to be amongst the toughest regulatory agencies globally, have become more stringent over quality and manufacturing standards.
- **Economic meltdown**: The Indian companies are also being adversely hit by the tight liquidity conditions, greater risks of realisation of receivables and overall reduction in demand due to a lower inventory turnover ratio.

Conclusion

- **Building competencies** : The imperative to succeed in the global generic market means building strong competencies across the entire value chain and constantly re-aligning business focus and costs as per changing market conditions.
- **Developing robust relationships with trade associations**: Building strong relations with trade associations becomes extremely important in highly competitive regulated markets.

Our Take

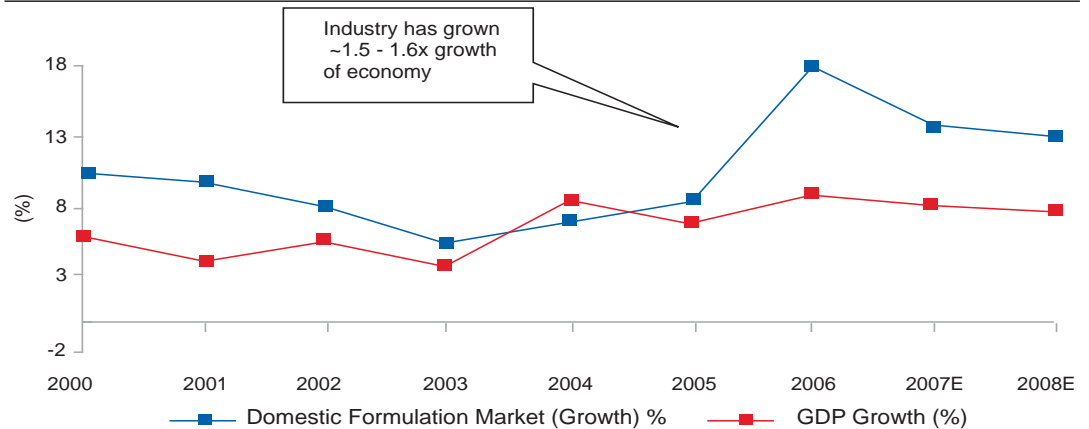
Generics are expected to continue to see robust demand led by macro-economic factors such as an ageing population, continuous pressure on healthcare budgets, increasing penetration of generic drugs and patent expiries. The governments world-over are still under immense pressure to lower healthcare costs. Against this backdrop, the US will continue to be the largest market for generics. Indian pharmacos are expected to comply with the stringent regulatory norms specified by the US FDA under the cGMP. On the other hand, with the US FDA setting up offices in India, the frequency of surprise inspection is likely to go up and requires adoption of 24x7 quality culture across areas. Meanwhile, the Indian companies are looking at products with high technology barriers and have limited competition to generate steady cash-flow. Generic sales, particularly to foreign markets, would remain the largest business segment for the Indian pharmacos.

Our Picks: Cadila Healthcare, Lupin and Ipca Labs

Domestic Market

India is the world's fourth largest Pharmaceutical market in terms of volume and thirteenth in terms of value. The Indian Domestic Formulation industry registered a CAGR of 14% during FY2003-08 from around US \$3.9bn in FY2003 to US \$7.7bn in FY2008 outpacing the Global Pharma Industry growth rate of 7%. Going ahead, the Indian Domestic Formulation market is expected to register robust CAGR of 12.2% over FY2008-13E to US \$13.7bn. By CY2015, India is expected to rank among the Top-10 global Pharmaceutical markets. The domestic pharma industry has been typically growing at around 1.5-1.6x the country's GDP growth. The Indian economy is expected to continue to outperform several developed and emerging economies, and the domestic drug market is expected to continue growing at double-digits and outperform several other key pharma markets.

Exhibit 5: Domestic Markets Growth v/s GDP



Source: CII-KPMG Pharma Summit 2009

This growth is expected to be driven by socio-economic factors such as rising income levels, increasing affordability, gradual penetration of health insurance and organised retail chains, increasing healthcare awareness in rural markets, increased willingness to pay for treatment in rural areas and rising prevalence of Chronic and Lifestyle diseases.

Key Challenges

- **Complex distribution system:** The domestic drug distribution system is multi-layered, fragmented and controlled by strong industry unions. Over the years, fragmentation of the distribution channel has increased.
- **Diverse market and managing rural penetration:** There is a wide disparity in living standards and infrastructure development across India and demand scenario differs significantly from region to region, making it a very complex market to enter.
- **Evolving regulatory infrastructure:** The introduction of product patents in India in 2005 has opened up the market for patented launches. However, the overseas players continue to believe that India's IP and regulatory system needs to be further strengthened.
- **Brand visibility:** The domestic drug market is extremely competitive with often ten or more brands existing for the same molecule. In such a market, brand allegiance by doctors is not easy. Brand building and loyalty is therefore a critical and challenging exercise in India.
- **Uncertainty in pricing policies:** The government needs to take the final call on the proposed Pharmaceutical Policy, which seeks to increase the scope of essential drugs under the purview of the DPCO from the current 74. This is expected to bring more clarity on the pricing scenario for companies operating in this market.

Conclusion

- **Ensure Optimal Reach:** For a profitable business model across the diversified domestic market, companies need to ensure covering maximum population at minimal investment. This can be done through comprehensive planning of the different business functions, viz. developing tailored marketing strategies for rural markets, hospital market, optimisation of supply chain management and sales force management.

Our Take

India is primarily a branded generic market with no player garnering more than 5% market share. We expect Chronic Therapeutic segments like Anti-Diabetic, CVS, CNS and Lifestyle diseases like Gastro-Intestinal to drive growth of the domestic markets going ahead. Also, Mass Therapies such as Anti-Infectives are likely to maintain their dominant position in the market. Hence, we expect companies with higher proportion of Chronic and Lifestyle diseases sales, better supply chain management and higher Revenue per sales force to lead the pack.

Our Picks: Cadila Healthcare, Lupin, Piramal Healthcare and Ipca Labs

Contract Research and Manufacturing Services

Global Innovators are under pressure due to a number of factors including growing patent expiries of major blockbuster drugs, price restrictions and slowdown in new product approvals and launches. Moreover, the decline in R&D productivity has resulted in further deceleration in bringing new blockbuster drugs to the market leading to difficulty in maintaining historic growth rates and Revenue levels.

India's value proposition has caught the attention of foreign companies. However, in spite of their potential, the Indian players have till date managed to capture only a low single-digit share of the global market. It is evident that leveraging this value proposition to realise maximum potential and generate Revenue streams is difficult because of the challenges involved in executing the projects and in building scale.

Key Challenges

- **Creating a reputation of a 'Reliable' partner:** Managing quality and delivery timelines are vital to become a reliable partner.
- **Long gestation period:** Gestation period in the CRAMS Segment is estimated to be 18-24 months from the time a contract is assigned to the commencement of supplies. This gap between Contract award to Revenue flow is primarily due to the lengthy regulatory process involved.
- **Continuous investment in Technology:** Indian companies are steadily expanding the scope of outsourced services offered to become integrated or one-stop-shop service providers. However, unlike other business segments, vertical integration across the value chain in the CRAMS Segment is a more challenging task because the players need to regularly invest in technology to sustain their competitive advantage. As a company moves into multiple offerings, managing the different segments simultaneously can be a complex task.
- **Managing the IP of the client:** Protecting the IP of the client is another critical factor for the success of a CRAMS business and trust plays a crucial role in the decision making process of selecting an outsourcing partner or vendor.
- **Ongoing economic slowdown:** Indian companies are coping with the short-term slowdown in orders from foreign players, which directly affects their Revenue flows.

Conclusion

- **Developing sustainable long-term relationships:** It is important to focus on developing a strong long-term network of clients and partnerships to build sustainable relationships. This can be achieved by winning the confidence of the clients by successfully executing big-ticket contracts.
- **Execution strategy:** An effective execution strategy is one that focuses on improving the quality of service, adhering to the delivery timelines and improving the cost structures while offering value-added services.
- **Strong technology platform:** Technology and Research play an important role in developing a successful CRAMS model. A company must work towards building capabilities in product and process innovation over time.
- **Regulatory adherence and ethical standards:** Strictly adhering to the highest regulatory standards and processes and having a strong ethical foundation that maintains client confidentiality and respects his IP are key determinants of the success of any company in this business segment.

Our Take

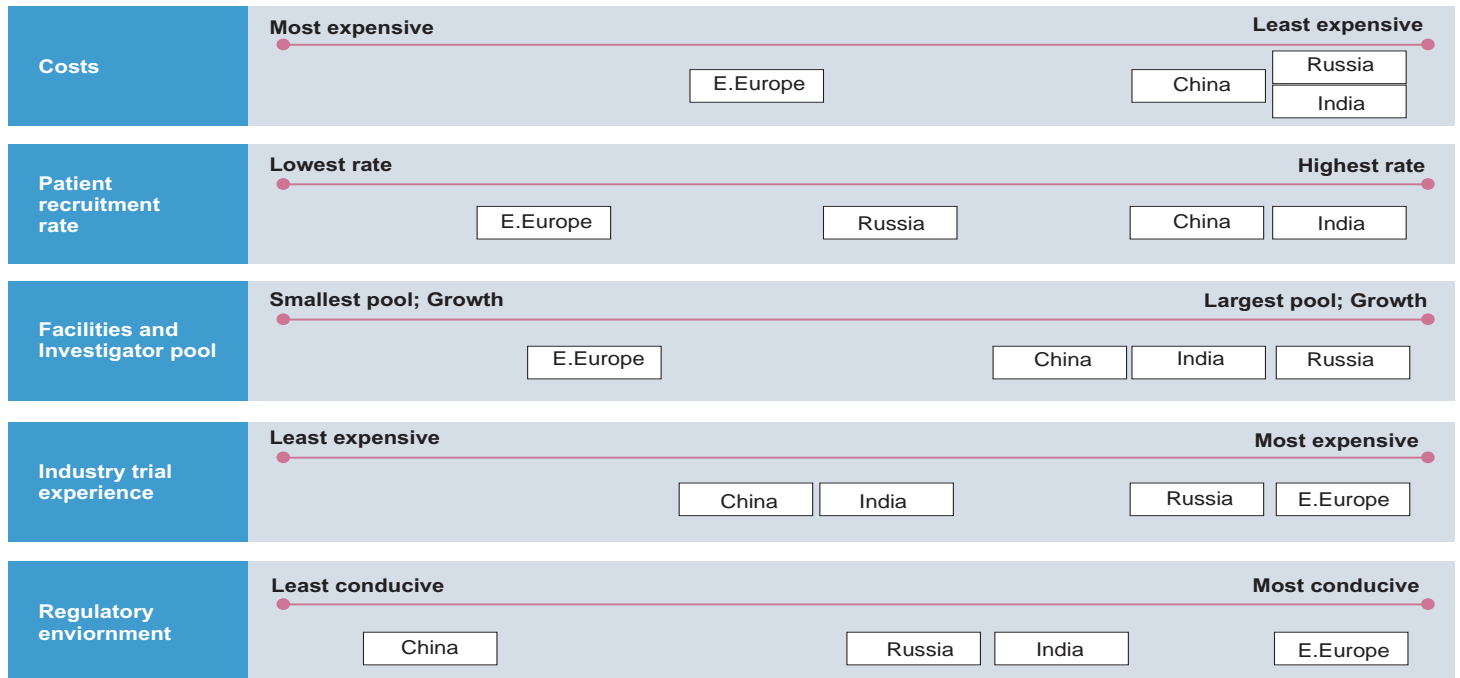
We continue to favour CRAMS. Though the Segment is witnessing near-term hiccups in terms of inventory de-stocking at the Innovators' end, which is expected to last for few more quarters, we expect this space to record secular growth over the long term and provide the players with immense opportunity on account of the challenges being faced by the Innovators and cost reduction benefits provided by the Indian players

Our Pick: Piramal Healthcare

Clinical Research Services

India is amongst the preferred options for foreign companies struggling to cope with the pressures of rising R&D costs, declining productivity and approval of new product launches. However, the motivation to outsource drug development to India goes well beyond the cost consideration. Recognising the value proposition India can offer in clinical research, foreign companies have, in recent years, laid greater emphasis on making it an integral part of their drug development value chain. This is evident in the increased collaboration between the Indian and foreign companies in the clinical development of drugs, the increasing number of multinational CROs setting up in India and the fast growing number of local CROs.

Exhibit 6: India's Clinical Trial Value Proposition



Source: CII-KPMG Pharma Summit 2009

Key Challenges

- **Building scale and credibility:** The Indian clinical research services market is still at a nascent stage. While the Indian CROs are working on building scale, they appear to be in a dilemma regarding their expansion plans. Clinical research and development demands require an extremely high level of commitment in terms of financial and time resources. It also demands the highest levels of safety, regulatory standards and quality processes. This means that the Indian CRO needs to build exceptionally high standards of credibility by demonstrating these skill-sets along with high standards of ethics to win clients.
- **Infrastructure bottle-necks:** CROs in India face an infrastructure challenge in terms of non-availability of:
 - Sufficient GCP certified sites,
 - Infrastructure for central laboratory services,
 - Supportive medical infrastructure, and
 - Shortage of trained and experienced clinical research personnel.
- **Managing patient recruitment and attrition:** In India, CROs face difficulties in recruitment in areas of oncology, diabetology, cardiology and neuro-psychiatry. They also face a challenge in recruitment of children and pregnant women

Conclusion

- **Building Credibility:** Building credibility in the eyes of the sponsor is an important factor in building a sustainable CRO model.
- **Building scale with a full range of clinical services:** A global footprint and broad range of service offerings can bring tremendous advantages to the CRO.

Our Take

CROs with presence in multiple geographies and providing a full range of services will be the key differentiator.

New Chemical Entity Discovery and Development

Absence of product patents in India for over three decades has laid the foundation of India's exceptional reverse engineering skills and strength in chemistry. Ironically, this has also been the primary reason for the absence of any indigenous new molecular entities. Indian companies have preferred to stay away from this business segment, which entails substantial investment in terms of money, time and other resources coupled with a very high risk of failure. Further, Indian companies have less experience and a lower knowledge base compared to the global Innovators, who have developed their resource pool of knowledge, talent, IP and finance.

Key Challenges

- **Experience in developing IP:** Being relatively new, Indian companies lack experience in developing their own molecules, especially the experience to take molecules through the advanced stages of development.
- **Funding constraints:** NCE Research is funded predominantly by internal funds generated by Indian companies from their generics business models. There is an absence of innovative funding models or private equity investment in this space. Given the high costs involved, high risk of failure and the long-term investment horizon, financial investors in India lack the experience and the risk appetite to invest in discovery research assets.
- **Limited infrastructure:** Unlike developed markets such as the US, India needs to develop research centres and allied infrastructure that can be shared by the companies and the academic institutions or the government for a PPP programme. Development of such shared resources can facilitate significantly in optimum utilisation of the already limited resources.

Conclusion

- **Funding options:** Indian companies can typically consider the following options for funding its new drug discovery pipelines:
 - Internal accruals,
 - Licensing agreements,
 - Raise capital, and
 - Government support.
- **Collaborative Research:** The level of experience and domain expertise the foreign players bring is critical. As a result, this collaborative model can mitigate the risks of failure, especially as the discovery program moves up the value chain.

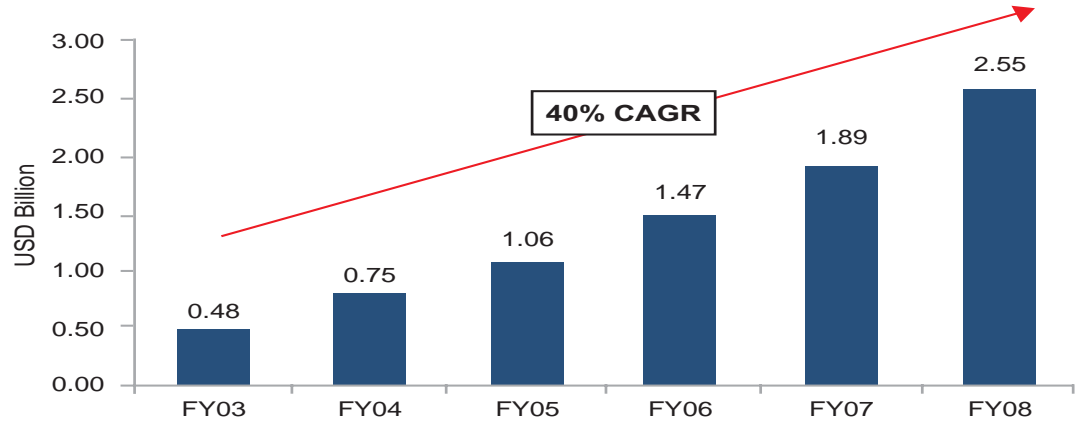
Our Take

We expect Out-licensing and Collaborative Research to be adopted by the India companies engaged in NCE Research given the substantial financial requirement and the low success rate.

Biotechnology

The Indian Biotechnology industry is still small, but registered a strong CAGR of 40 % during FY2003-08. Moreover, the Indian biotech players have made their presence felt in the global industry. Thus, based on India's strong value proposition, the country's potential to emerge as a leading player has been well accepted globally

Exhibit 7: Biotech Industry - Market size



Source: CII-KPMG Pharma Summit 2009

Challenges

- **Product development** : Product development in biotechnology is a more challenging activity than developing a small molecule generic. This is because a biosimilar exhibits higher molecular complexity.
- **Funding issues**: Lack of adequate funding can be a serious growth inhibitor for any company and is particularly relevant to Indian biotechnology companies, many of which are relatively new start-ups.
- **Penetrating Regulated markets**: The global biosimilars market appears to be very attractive, especially as the regulatory pathway has either already opened up in some of the biggest markets, or is in process of doing so. However, penetration into these highly regulated markets is challenging. Given the high regulatory standards and the overall market dynamics, launching a biosimilar in these markets is a complex process. It demands high-level capabilities at every stage from development to commercialisation.

Conclusion

- **Collaboration**: Biotechnology is a relatively new industry with a large number of start-ups. Hence, it is even more important for the government, education institutions and financial investors to collaborate closely with industry players to address the aforementioned challenges and build a strong industry base.

Our Take

While biosimilar could be the next wave for generics, regulatory uncertainty in the US is the main hindrance. Though the EU, Japan and other developed markets have approved legislation for biosimilars, regulatory clarity in the US market would be the major catalyst, which would entail further investment in the Segment.

Fund Management & Investment Advisory	(☎ 022 - 3952 4568)	
P. Phani Sekhar	Fund Manager - (PMS)	phani.sekhar@angeltrade.com
Siddarth Bhamre	Head - Derivatives and Investment Advisory	siddarth.bhamre@angeltrade.com
Devang Mehta	AVP - Investment Advisory	devang.mehta@angeltrade.com
Research Team	(☎ 022 - 3952 4568)	
Hitesh Agrawal	Head - Research	hitesh.agrawal@angeltrade.com
Sarabjit Kour Nangra	VP-Research, Pharmaceutical	sarabjit@angeltrade.com
Vaibhav Agrawal	VP-Research, Banking	vaibhav.agrawal@angeltrade.com
Vaishali Jajoo	Automobile	vaishali.jajoo@angeltrade.com
Harit Shah	IT, Telecom	harit.shah@angeltrade.com
Shailesh Kanani	Infrastructure, Real Estate	shailesh.kanani@angeltrade.com
Anand Shah	FMCG , Media	anand.shah@angeltrade.com
Deepak Pareek	Oil & Gas	deepak.pareek@angeltrade.com
Puneet Bambha	Capital Goods, Engineering	puneet.bambha@angeltrade.com
Sushant Dalmia	Pharmaceutical	sushant.dalmia@angeltrade.com
Rupesh Sankhe	Cement, Power	rupeshd.sankhe@angeltrade.com
Param Desai	Logistics, Shipping	paramy.desai@angeltrade.com
Sageraj Bariya	Fertiliser, Mid-cap	sageraj.bariya@angeltrade.com
Viraj Nadkarni	Retail, Hotels	virajm.nadkarni@angeltrade.com
Jai Sharda	Mid-cap	jai.sharda@angeltrade.com
Amit Vora	Research Associate (Oil & Gas)	amit.vora@angeltrade.com
Laxmikant Waghmare	Research Associate (Metals & Mining, Cement)	laxmikant.w@angeltrade.com
V Srinivasan	Research Associate (Power, Mid-cap)	v.srinivasan@angeltrade.com
Aniruddha Mate	Research Associate (Infra, Real Estate)	aniruddha.mate@angeltrade.com
Shreya Gaunekar	Research Associate (Automobile)	shreyap.gaunekar@angeltrade.com
Mihir Salot	Research Associate (Logistics, Shipping)	mihirr.salot@angeltrade.com
Chitrandga Kapur	Research Associate (FMCG, Media)	chitrandgar.kapur@angeltrade.com
Vibha Salvi	Research Associate (IT, Telecom)	vibhas.salvi@angeltrade.com
Jaya Agrawal	Jr. Derivative Analyst	Jaya.agarwal@angeltrade.com
Amit Bagaria	PMS	amit.bagaria@angeltrade.com
Sandeep Wagle	Chief Technical Analyst	sandeep@angeltrade.com
Ajit Joshi	AVP Technical Advisory Services	ajit.joshi@angeltrade.com
Brijesh Ail	Manager - Technical Advisory Services	brijesh@angeltrade.com
Vaishnavi Jagtap	Sr. Technical Analyst	vaishnavi.jagtap@angeltrade.com
Milan Sanghvi	Sr. Technical Analyst	milan.sanghvi@angeltrade.com
Mileen Vasudeo	Technical Analyst	vasudeo.kamalakant@angeltrade.com
Krunal Dayma	Technical Analyst	krunal.dayma@angeltrade.com
Sanket Padhye	AVP Mutual Fund	sanket.padhye@angeltrade.com
Pramod Rathod	Research Associate (MF)	pramod.rathod@angeltrade.com
Poonam Jangid	Research Associate (MF)	poonam.jangid@angeltrade.com
Commodities Research Team		
Amar Singh	Research Head (Commodities)	amar.singh@angeltrade.com
Samson P	Sr. Technical Analyst	samsomp@angeltrade.com
Anuj Gupta	Sr. Technical Analyst	anuj.gupta@angeltrade.com
Girish Patki	Sr. Technical Analyst	girish.patki@angeltrade.com
Abhishek Chauhan	Technical Analyst	abhishek.chauhan@angeltrade.com
Commodities Research Team (Fundamentals)		
Badruddin	Sr. Research Analyst (Agri)	badruddin@angeltrade.com
Reena Wallia	Research Analyst (Base Metals, Energy Complex)	reena.walia@angeltrade.com
Vedika Narvekar	Research Analyst (Agri)	vedika.narvekar @angeltrade.com
Nalini Rao	Research Analyst (Agri)	nalini.rao@angeltrade.com
Bharathi Shetty	Research Editor	bharathi.shetty@angeltrade.com
Dharmil Adhyaru	Assistant Research Editor	dharmil.adhyaru@angeltrade.com
Bharat Patil	Production	bharat.patil@angeltrade.com
Dilip Patel	Production	dilipm.patel@angeltrade.com

Research & Investment Advisory: Acme Plaza, 3rd Floor 'A' wing, M.V. Road, Opp Sangam Cinema, Andheri (E), Mumbai - 400 059

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