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We scaled back operations at our Mumbai R&D unit: Piramal

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Singapore: The global CRAMS (Contract Research and Manufacturing Services) segment is becoming intensely competitive. Cost pressures and heightened regulatory intensity pose key challenges to this sector.

In his gripping interview with BioSpectrum's Raj Gunashekar, Mr Vivek Sharma, CEO-pharma solutions division, Piramal Enterprise, shares his exclusive views on the company's organic and inorganic growth plans, trends shaping up the industry, investments in new technologies, R&D cost pressures, and the impact of Mumbai R&D unit shut down last year.

In January 2015, the company acquired US-based specialty pharmaceutical contract manufacturer, Coldstream, an eight-year-old organization with a focus on clinical trial to commercial-scale manufacturing of sterile liquid and lyophilized parenterals and injectables.

Mr Sharma says that the contract manufacturing market for sterile injectables is expected to grow at an extremely fast rate.

The CRAMS sector worldwide is highly fragmented, and is estimated to be growing at a CAGR of 7 percent.

He reveals that the company has significantly invested in ADC (Antibody Drug Conjugate), a new technology.

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"ADC is an exciting technology which we believe has a lot of potential. However it remains a relatively new technology. Globally there are only two ADC products that have been commercialized. As more ADCs get commercialized, we would see significant growth in this segment, in both regulated markets and in emerging markets," he highlighted.

"Our recent acquisition of Coldstream is a step towards enhancing our presence in this segment. Coldstream is a very high quality operation and has been able to build significant customer relationships and track record for sterile products. We see

this as a great platform for growth in our pharma solutions business," he explains.

He feels that this acquisition will allow Piramal Enterprise to move further into the injectables market segment and have a strong synergy with its existing pharma solutions business.

Coldstream's use of isolator technology impressed Piramal, offering a foundation for expansion of the facility to provide large scale commercial manufacturing including production of highly potent compounds.

Piramal's pharma solutions business is also on the lookout for investing in niche technologies.

"Our acquisition of Coldstream was a step in this direction which gave us access to sterile injectables and differentiated expertise to formulate and manufacture high potency and cytotoxic compounds including ADC. We are also looking at technologies in the API (Active Pharmaceutical Ingredient) space that would enable us to handle cytotoxic compounds," he points.

Globally, pharmaceutical companies are experiencing the effect of 'patent cliff'. A huge number of drugs will be going off patent soon.

New launches are not able to make up for the loss of sales from drugs which are going off patent.

"At the same time, R&D productivity as measured by average cost or new molecule entity, has been rising. In addition to this, raw material price increases and wage inflation is further adding to cost pressures. Finally, in regulated markets, we are also seeing a push towards generics from healthcare and insurance companies. These trends are translating into strong growth prospects for CRAMS providers, and we are optimistic that we are best positioned to leverage on this opportunity effectively," Mr Sharma summarizes while talking on the current happening trends in the pharma industry.

As for the company, R&D is considered to be a key element in its strategy, "We continue to optimally invest in people and infrastructure to augment our R&D expertise," Mr Sharma remarks.

For its pharma solutions business, North America and Europe have been its top performing markets and the company expects this trend to continue in 2015 as well.

"CRAMS business centres around big pharma and emerging pharma companies based in North America and Europe. Our revenues therefore are expected to be centered on these geographies. However, we are a product centric business and are flexible enough to explore opportunities in emerging markets based on our customer requirements," he states.

Mr Sharma observes that regulators globally are increasing the frequency and intensity of audits and inspections in a bid to ensure that pharma products are completely safe for end users.

When asked about the company's growth plans, he stressed that the company remains committed to growing its business, both organically and inorganically,

"Inorganically, we are always exploring niche buys as long as they provide us complimentary capability or give us a competitive advantage in the market place. We are increasingly being approached by companies with marketing capabilities to partner with them so as to leverage our leadership position, such as in ADC and formulations development. We are also looking to add capabilities in our API business. Whilst we scout for inorganic opportunities, we also remain confident of strong growth in our existing business and remain committed to making necessary investments to meet our goals," he comments.

For now, Mr Sharma says that the company continues to remain optimistic about its entire pharma solutions business.

"We have a broad set of offerings spanning from drug discovery & development to commercial manufacturing of off patent APIs and fixed dosage forms. We will continue to focus across these areas while investing in specialized services such as ADCs and biocatalysis. In Piramal Critical Care (PCC), we have significant market share in multiple geographies and we expect to grow further within this segment while expanding into related areas," voices Mr Sharma.

Commenting on Piramal's Mumbai R&D unit shutdown in August 2014 and its impact on the business, Mr Sharma expresses, "We scaled back operations at our Mumbai R&D unit that was handling our own new chemical entities (NCEs). We continue to

do development work for our customers in the CRAMS space. This move will actually benefit the business since it eliminates any apprehensions that customers may have with respect to conflicts of interest and IP (intellectual property) protection."