CREATING AN INTEGRATED OUTSOURCING WORLD: Piramal CEO Talks Quality, Capability And Cost

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From global big pharma with established brands, to biotechs with rapidly expanding pipelines, life sciences companies all have similar challenges – optimizing their costs, consolidating their suppliers, and speeding their products to market. In expectation of achieving these goals, firms that have never outsourced their products are now doing so, and many are collaborating with contract development and manufacturing organizations such as Piramal Pharma Solutions. CEO Vivek Sharma believes this is a positive and growing trend, despite the suggestion from some who say the industry is pulling back, and he provides company data to back it up. With around 50 integrated programs that include drug substance and drug product, a track record for high quality, and worldwide capabilities, Piramal is planning for the future: investing capital at every single plant, expanding capabilities, and talking acquisitions.

What would you say is the current growth trend for the contract development and manufacturing market?

At the macro level we are excited with the market trends. If we look at the business drivers for Contract Development and Manufacturing Organizations (CDMOs) from a customer perspective – every company with whom we interact has similar challenges – they are all trying to optimize their costs, and get their products out to the market faster. From a large pharma perspective, we see consolidation of their supplier base, and internal restructuring leading to less resources to manage more programs. This has led to preferred partnerships between big pharma companies and CDMOs that can meet their global needs. In parallel, with biotechs, their funding is growing, and that capital is invested on innovation, and on discovering new medicines. Post discovery, these biotech firms are also increasingly looking toward CDMOs to support their clinical development and commercial requirements.

To summarize, the health of the industry is excellent, and we expect CDMOs to benefit from the partnership approach of our customers.

How much are you involved in biotech at present? The product portfolio across the industry is shifting very heavily in that direction.

A significant proportion of our growth is coming from young biotech companies that are nimble and working on developing cutting-edge medicines. These firms are doing well, armed with significant capital, and have strong pipelines. Biotechs are different, in that they look for a more personal relationship with the CDMO: they want to be comfortable that the CDMO will give their "single product" the same level of attention that a CDMO may give a large pharma. At Piramal, we have worked diligently at building our relationships with biotechs, and are pleased that over the past 24 months, we are the "partner of choice" for over 100 of these young companies.

Your services extend all the way from discovery to launch. Are you seeing a particularly strong growth trend in one part of those, say manufacturing or discovery?

While the discovery business is smaller in size, it is the business area where we on-board a number of new customers. This capability allows us to build relationships early and then transition these into development. We have a strong pipeline across all clinical phases with over 150 molecules in clinical development for partners, including over 30 in Phase III. We also expect to launch 10 New Chemical Entities (NCEs) for our customers this year. From a therapeutic area perspective, our fastest growth is in the area of oncology, where several of our customers are invested, and also because we have some unique offerings to address this disease area.

Would you say that general outsourcing is just as strong as it has been in recent years? As you are aware, there have been questions about issues such as data integrity and there is a suggestion that perhaps the industry is pulling back a bit from using outsourcing companies, other than within the US and Europe.

If we have seen any trend, it is to the contrary. Our growth numbers – on both topline and EBITDA – are higher than the industry average. If I project forward, we have a fertile late-development pipeline (30+ Phase IIIs plus 10 potential launches this FY) – hence we are investing capital and expanding almost all our 12 sites located across the globe. There are several factors that have propelled our growth, some of which are market driven, and some of which are Piramal specific. For example, our track record when it comes to customers has been excellent. Our quality record is impeccable; it's probably one of the best you will find within the industry. Of the five regulatory inspections we had last year, four had no observations. So in general, all of our sites are growing, irrespective of their location, as they have

all delivered on customer satisfaction, and on quality.

As far as your question on Asia, Piramal is global; we are the only CDMO in the world that has roughly half its sites in the East and half its sites in the West. As long as our customers seek external partners and outsourcing we are agnostic about where they outsource to. We want to be local for the firm that is launching the drug – that's the whole ethos behind our company.

It's interesting you mention integrated cancer development. What are the particular challenges that you face in the cancer segment?

We view integrated cancer solution development as an opportunity. One in four compounds that are in development are in cancer, and we are one of the few companies to have a fully integrated oncology platform. We have over 65 oncology programs that are ongoing – from early development through commercial launch.

Within the Piramal Pharma network, we have one of the most highly reputed high-potency API sites in the world, at Michigan, in the US. We are now expanding the high-potency API capability to our Toronto (Canada) site, providing customers with additional flexibility and capacity. I should also point out, that for several multibillion-dollar commercial medicines, we are the sole supplier of the API – a testament to the trust that our customers place in us. Our customers working with us on oncology API development are keen on leveraging the finish capabilities in Kentucky, and now have an integrated solution that includes both API and drug product. For customers interested in developing Antibody Drug Conjugates (ADCs) for cancer, our conjugation facility in the UK, and the fill finish in Lexington, KY, offers end-to-end solutions. By the end of the year, we expect to augment this offering, by manufacturing the payload and the linker for ADCs from our facility in Michigan. Finally, we are looking to add oral oncology and pre-filled syringe capabilities to meet our customer needs.

Offering integrated services, presumably that lends itself to more strategic partnerships with your clients. What do you see as the trend now in relation to pharmaceutical industry consolidation? Is that driving more strategic alliances, and what's your advantage in that respect? What's the advantage for your clients?

Let's talk from a large pharma perspective. It enables large pharma companies to achieve the objective of consolidating suppliers, and managing programs better. It shortens project timelines and reduces costs. The key for success though is to ensure that all the individual offerings be world-class. Customers will not give the business to you just because you are integrated, if one of the supply verticals is not up to par.

We currently have 50 active integrated programs and we are seeing the interest continue to grow. Let me give you a few examples. Piramal is the preferred, integrated R&D partner for one of the largest pharma companies in the world, based out of Europe; we are the only company they will work with in this fashion. Why are they doing it? Because we have been able to demonstrate that we can develop the products faster, and more efficiently, saving them both time and effort.

As for biotechs, one good example is a small Boston-based partner that is carrying out all components of its supply chain for its flagship product – that is launching next year – at Piramal. We supply their API, forward integrate by manufacturing the drug product and also manage their clinical trial supply. Again, the reason they chose us was our track record, and our commitment to meet their future needs.

Internally, we have optimized our systems, modified our structure, hired the right talent, and added technology, to ensure that our customers have a seamless experience on any integrated program.

The East-West nexus that we discussed earlier also plays a key role on integrated solutions. For example, when a customer comes to us for integrating the API and drug product, we may, in consultation with the customer, do the first five or six steps of the API out of India and then finish the regulated steps out of North America. This offers our customers the benefit of an internally controlled supply chain and also real cost benefits. On the drug product side, based on customer interest, one can do the initial development out of our facility in India, while carrying out the manufacturing out of one of our sites in the West.

The other reason that firms come to integrate with one company is that it aligns drug substance availability to drug product capacity. If you are working with two different suppliers, and your API is delayed, you may miss your drug product manufacturing slot leading to further challenges. If you are working with one partner, for example Piramal, we would adjust for any delay on the API, and adjust our drug product manufacturing schedule accordingly to minimize time overruns. This helps immensely when customers have patients awaiting the drug following clinical enrollment.

What other unique capabilities do you have to offer your clients?

From a science perspective, we are one of the world leaders in ADC solutions. We have injectables manufacturing in North America, an area that is growing rapidly. We have high potency. We have a global footprint. We have a unique collection of offerings and sites, which work together as one unit, allowing us to address the needs of a variety of customers.

The integrated offering, and our track record of success, is a distinct differentiator. We begin at the contract stage, with integrated documentation and legal paperwork to minimize time, and then forward integrate that with a seamless solution that includes systems, capabilities, people and technology. You save time. You save costs.

Finally, our biggest differentiator is our customer centricity initiative. We see ourselves as a service industry, only that in our industry, we offer science-based solutions to develop innovative medicines. We exist to understand our customer needs and how we can help their customers, who are the patients they are trying to serve.

Over the next five years, what are your plans, in terms of new capabilities and what you think the market is going to be doing over that period?

We are excited about what we have achieved over the last three or four years due to our focus on the customer. We have significantly extended our capacities and offerings to serve our customers better. We expect to continue to add capital to meet our customers' future needs. These investments could be organic, or could involve acquisitive growth. Internal capital is being put into every single plant that we have, as we model our customer late-stage pipeline, and ensure that their commercial needs are met. Acquisitive capital may be used to add more unique capabilities that will allow us to serve additional customers.