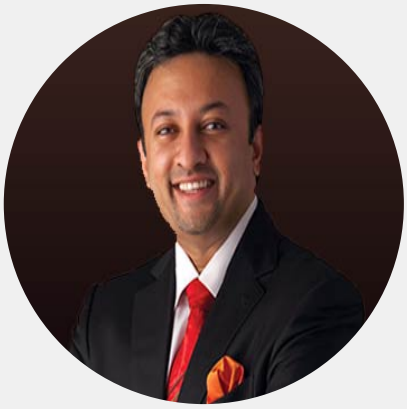
Sharvil Patel – Managing Director, Zydus Cadila



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As managing director of India's fifth largest pharmaceutical company, Zydus Cadila's Sharvil Patel shares his insights on his impressive internationalization strategy with a special focus on the US where Zydus

recently received permission to conduct Phase II clinical studies of Lipaglyn, the first drug to treat patients with nonalcoholic steatohepatitis (NASH).

Zydus Cadila's year has started with the acquisition of US-based Sentyln Therapeutics, what was the rationale behind this move?

We have always been strong in the generic industry and we felt that it was about time to build a specialty care franchise too. Sentyln is a company specializing in marketing of products in the pain management segment. Its acquisition gives us the opportunity to focus on a few specialty areas that we have shortlisted, notably neuropathic pain, oncology, dermatology and gastro intestinal. Through this acquisition we are looking to enhance our commercial presence in terms of how to tailor products and place them on the market but, more importantly, what we learned from this is to look at more assets. The team that we have in the pain management segment is very good at taking small brands and turning them mid-size. Essentially, we have been able to seize many more opportunities than we used to. In the foreseeable future we hope to add more sales representatives and scale up this specialty business in the US.

Looking at your internationalization strategy, what are the key markets for Zydus Cadila?

For the time being, India is a crucial market for us since we have a strong presence here and we are at the top of the rankings in the country. It is growing and, accordingly, there is still a lot of potential for our continuous growth from a business point of view. We are well-established and do not have ups and downs which makes running a business much more comfortable. This thriving environment helps us position ourselves and scale up products in India and now, with the acquisition of US-based Sentyln, we are looking to reach the US market which accounts for the 60 percent of the entire generic ecosystem.

Other than that, we are looking to internationalize in emerging markets, because this is where we see growth coming from. For instance, in LATAM we are in Brazil and Mexico, whereas in the African continent we believe South Africa is a strong market to make investments alongside places like Algeria or sub-Saharan countries like Kenya or Uganda, which we deem very interesting from a business perspective.

Lipaglyn is India's first new chemical entity (NCE) and has investigational new drug status with the USFDA. You have recently received permission to conduct Phase II clinical studies in the US. How is it going so far?

In India we are doing very well so far with the launch of the brand and we are covering about 100,000 patients. Our aspiration is to have the drug registered in critical markets across the world. Currently we have three Phase II studies in the US and another four in India. NASH, which is the indication for Lipaglyn we are currently working for, is an area of unmet healthcare need as there are currently no drugs approved for the treatment of the disease in both emerging and developed markets. We are planning to launch the drug either through ourselves or by licensing it out. The product has significant and differentiated effect on hepatic steatosis, while it shows all other beneficial effects. We are very confident that we will be successful because of the current data and clinical leadership that we have in India. We are looking to launch it in 2019-2020.

India has long been renowned as a manufacturing powerhouse and today we see many leading companies investing in R&D. India's five top drug makers together spent a

record of 1.2 billion USD in 2017. What is the importance of R&D for Zydus Cadila?

I believe that it is not a matter of how much money you spend, it is a question of where you are focusing on and how successful you are in those areas. In India, beyond producing generics, you would need to do differentiations. What everyone is doing is investing and incrementing innovation by coming up with new formulations and filling the gaps in therapies. However, the real issue is access of products such as vaccines and biosimilars, partly because there is a technology barrier. We are working on these areas to ensure we capture this opportunity. Our long-term vision is to have an RNC and biologics – for one of the latter we are conducting Phase III studies. I believe that most companies of a certain size should be to do it.

What is the biggest challenge faced by the industry in the country?

The last two years have been slightly turbulent because of the policy changes and the pricing challenges which caused a certain level of disruption. Despite the difficulties we encountered, the Indian pharmaceutical market has been growing double-digit and we will experience a growth of about 12 percent moving forward. Price pressure is present in the US and it is essential to have a rich portfolio to overcome the hurdle – which we feel we have in India. On a different note, protectionism is emerging more and more with companies requesting and establishing their manufacturing plants in the country in which they operate. An example of countries pushing for having local manufacturing facilities are Indonesia and Vietnam. I would like to reiterate that if you have a good and comprehensive portfolio, it is less problematic to overcome challenges. We manufacture, for instance, largely in India but we also have two facilities in the US – one in Saint Louis and one in Maryland – we have one facility in Brazil and in Europe we are in Germany – even if it is not traditional pharmaceuticals.

Have you been through some of the FDA scrutiny that we have heard from a few interviewees and which we discussed with Mr. Shah from the Indian Pharmaceutical Alliance?

A large part of the products currently available and consumed in the US are made in India, so it is nothing surprising that India will have a bigger number of audits. FDA put a lot of emphasis on compliance over the last couple of years as they want to improve compliance standards not only for India, but also for all the markets across the world. In fact, most companies are adapting to

these standards – we had seven audits in the past seven months and they have been successful up to this point. However, it is an ongoing journey – if anything, it keeps you on your toes.

The global *biosimilars market* is expected to reach USD 10.90 Billion by 2021 from USD 3.39 Billion in 2016. What opportunities do you recognize for Indian drug makers and Zydus in particular?

Biosimilars are at the core of our business and we started working on them in the early 2000s. As far as the domestic market is concerned, we have been quite successful as we have developed and commercialized nine products. Our global strategy is now to outlicense in many of the emerging markets to local large companies in countries such as Russia, Brazil and Colombia. Biosimilars are very interesting as access is very poor and prices are mostly high in many markets around the world. Our mission is to enhance access and bring them at an affordable price.

Do you see any opportunities for smaller players to become like Zydus?

As I am sure you have noticed by now, the pace changes very fast and being big does not equate good and being small is not a synonym for unproductivity. It merely depends on the right time and the right products in order to seize every opportunity. I think it is getting harder to do business because of competition for both big and small organizations, meaning that it will be tougher to have better margins. Huge consolidation leads to lower pricing which, in turn, leads to higher risks and success is dependent on many factors – FDA compliance among others. Nevertheless, there are many companies in India developing their own innovative portfolio.

Your father was the first one to recognize the importance of business units within the organization and implement these to facilitate the growth of Zydus Cadila. What would you say is your vision for future winning organizations?

Firstly, as businesses are getting more and more complex, it is absolutely fundamental to make internal units independent and to ensure that the dedicated people heading those unites have an interest in growing, developing them with committed strategies. As our company becomes larger we try to keep the business sustainable by separating the various entities that constitute it. I reckon that this accelerates the decision-making process which can only improve if you have a fully

independent operational structure.

What are your strategic priorities at the moment?

In the first place, I would like to enhance our vaccines and our biologics portfolio along with research and development. We currently have 18 vaccines launched as well as nine prequalified WHO ones which allows us to participate in the global tenders. Definitely both the private and the public vaccines markets are within the scope of our strategic interests, as well as expanding to the US. Furthermore, special focus will be given on compliance and enhancement of productivity in every area. To this purpose, we are looking to run programs on how to improve productivity across the organisation. Our aspiration has always been to become a research driven pharmaceutical company and we stated this vision in 1995 with the aim of accomplishing our mission by 2020. I think that we have delivered on the commitment that we made back then.

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