BioSpectrum the business of Bio & Health Sciences

Master of Innovation

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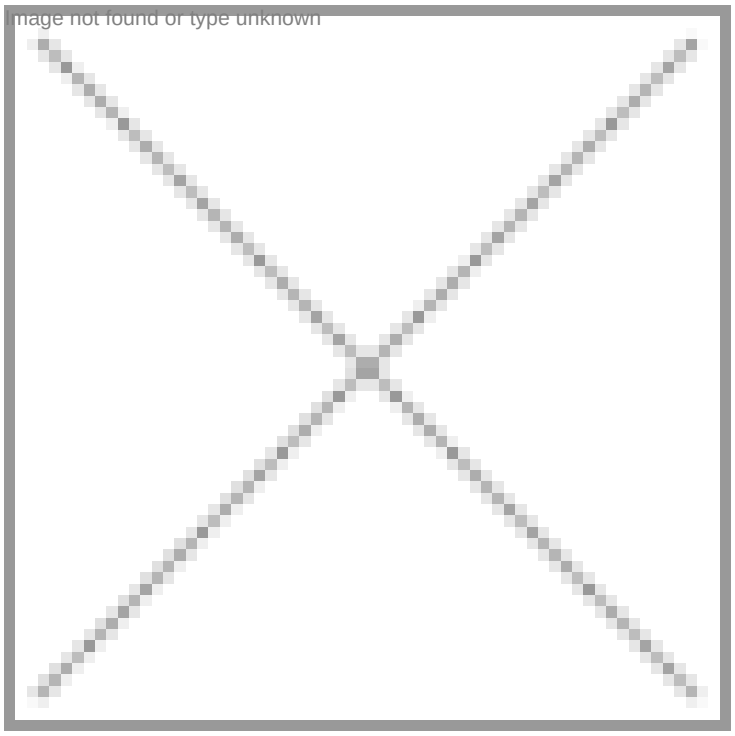
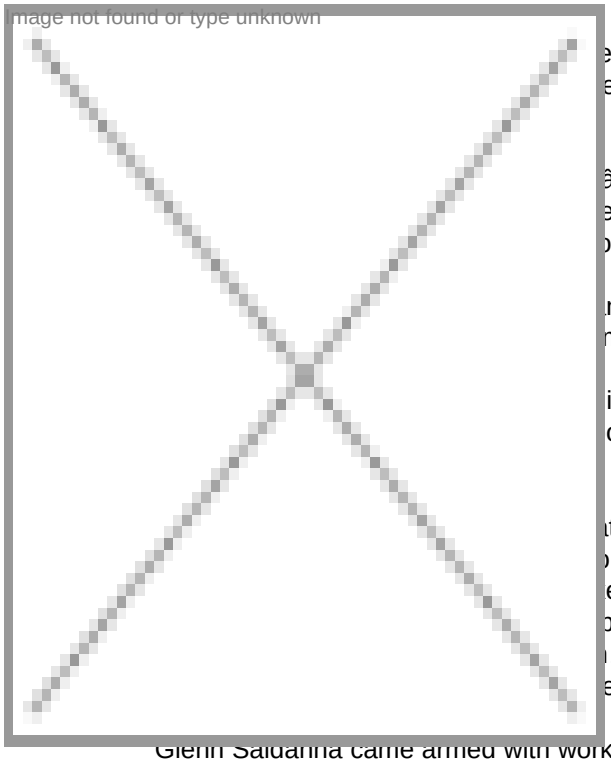


He made a quiet entry into Indian life sciences industry in 1998, taking over the reins of Glenmark Pharmaceuticals. Today, Glenn Saldanha, MD & CEO of Glenmark Pharmaceuticals has set a benchmark with a robust, burgeoning pipeline of NCEs and NBEs



Glenn Saldanha's is a daring story of venturing into the high risk space of ecade when innovation was the most-used buzzword but there were few who took ere 10 years of work is just a blink-and-a-half in the product cycle, and failure a

â€“ in the process â€“ has earned for Indian life sciences industry a place on the ess. This, aside from growing his company manifold. In fact, to over $500 millio n (82.8 crore) in 1998, when he took charge as director.

nded rapidly in discovery research of small molecules and biologics, along with mination and conviction has been instrumental.

is detractors are now eating their words with Glenmark securing its position as a oth in small molecules and biologics.

tions in 1977 under Glenn Saldanha's father, Gracias Saldanha. Named after his r focused on the manufacturing and marketing of formulations products in India. In evenpoint, recording pr its of 26,363.72. Subsequently, the company started bally. And by 1981, the turnover touched the 1 crore mark. However, it was only 1998 that Glenmark Pharmaceuticals ascent on the steep growth curve began. ear 2000.

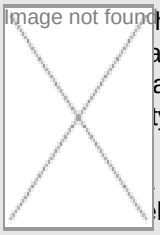
Glenn Saldanha came armed with work experience of few years in the US, where he put in time with Eli Lilly and Pricewaterhouse Coopers. His stint with these two well-known MNCs had a pivotal role in shaping his beliefs and outlook towards the business. The exposure in the US also provided him an opportunity to work with global pharma giants, such as Merck, Bristol Myers Squibb and Johnson & Johnson. â€œMy roots come from my early years as an MBA student in New York University; and working with Eli Lilly and Pricewaterhouse Coopers where, I acquired most of my skill set, which gave me a head start in India. Consulting to the pharma business gave me a good insight into how the business works,â€? says Saldanha.

He joined the company with a two-fold strategy in mind. â€œIn 1998, about 99 percent of our business came from India. My game-plan was to globalize our name and generate as much revenue as possible through generics and re-invest some of the money in innovation and intellectual property. The strategy was to bring out our products, out license it to the US, Europe and Japan; and retain the rights with us for the rest of the world (RoW), either by exclusive or co-marketing rights and build infrastructure in RoW markets. So that when the molecule comes to market â€“ we would already have an infrastructure in place,â€? he reveals.

The company has been growing from strength-to-strength. For FY2009-2010, Glenmark clocked an annual turnover of ove 2500 crore, which was a growth of 18 percent over the previous fiscal. In the current fiscal it will easily c ss 3000 crore. It has operations in 80 countries, with employee strength of nearly 7,000 people, globally. Glenmark today has five research facilities, 13 manufacturing facilities in four countries and seven new molecules in clinics.

The company's New Chemical Entity (NCE), Crofelemer, a first-in-class anti-diarrhoeal drug, has successfully completed phase III trials for HIV-related diarrhoea. Glenmark has exclusive marketing and distribution rights for this compound for multiple indications across 140 countries. Saldanha anticipates approval of Crofelemer in India in 2012.

the biologics space, Glenmark's lead products GBR 500 and GBR 600 have entered clinics. Saldanha is known for his umen in signing significant licensing deals with some of the big MNCs. In 2010, the company entered into two landmark als. Its subsidiary in Switzerland granted a license to Sanofi-aventis for developing vanilloid receptor and GRC15300. The latter is currently in phase I clinical development for treating diabetic neuropathic pain and osteoarthritic pain. The subsidiary has also been granted a worldwide license by Italian-based company, LayLine Genomics (LLG) to its entire IP portfolio in the body BXL1H5. This represents another first-in-class opportunity for Glenmark.



hers at Glenmark focus on developing antibodies. Glenmark is the first Indian at has a novel, first-in-class novel ty in the clinics in the US. We are platform technologies to develop format specific for Glenmarkâ€?

l Buschle, president (biologics),

Glenmark Pharmaceuticals

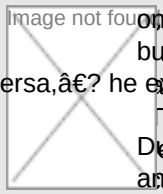
First Person

Saldanha is one of the pioneers in India's R&D story a success. He has been a leader in making major licensing deals has been careful in selection of its molecules by taking all the stakes, and considerationâ€?

-Sujay Shetty, associate director (pharma & life sciences), PricewaterhouseCoopers, India

Saldanha's focus on pharmaceutical generics and drug discovery research to cull the nine years.

-Tapan Ray, director general, CII



Saldanha's vision of an innovation-led business and his drive and passion to achieve as been a key differentiating aspect for Today, the fact that Glenmark has ecules in clinical development for al needs is a significant achievement for an Indian organizationâ€?

-AS Moharty, executive director, Glenmark Pharmaceuticals

other companies were looking to capture a sizable share in the generics space, Saldanha saw that to achieve a healthy growth curve in future, Glenmark needed a paradigm shift towards the high-risk space of novel drug discovery research. This was around the time when India was a signatory to the GATT and was moving towards the product patent regime. â€œWhat makes Glenmark unique is that we have been extremely passionate about innovation, since the beginning of this decade. There was a great opportunity for India to move into this space because of the low cost of R&D; and we used that opportunity to the maximum advantage,â€? he recollects. Glenmark took the IPO route, getting listed in 2000. The company got oversubscribed 65 times and its market capitalization touched $40 million. It then invested the proceeds in setting up an R&D center in Mumbai to carry out innovative drug discovery research, marking its first step into NCE discovery

This R&D center is spread over 1,25,000 sq ft with over 200 scientists working on multiple targets in broad therapeutic areas and have been responsible for discovering 13 NCEs in a short span of

The company thus pursued its innovation research with small molecules from 2000-2004. While domestic companies were on the run to hive out their R&D units, Saldanha opted to restructure his business into two clear divisions â€“ specialty and generics. â€œThere are lots of synergies between R&D and the branded generics side of the business. Our mix is very clear â€“ we have Glenmark Generics, which focuses on branded generics and Glenmark Pharma, which is our innovation engine. The reason for not hiving out the business is that there were times when our R&D division supported the generics side of the business and vice-versa,â€? he explains.

During 2005-2006, Saldanha realized that the innovation sphere was changing - and the move was towards antibodies and biologics. â€œWe saw that the company needed certain skill sets in biologicals. This prompted us to venture into it,â€? he says. The company then set up a facility in Switzerland, Glenmark Pharmaceuticals SA, dedicated to biologics research.

Why Switzerland? â€œTo counter the skill set gap in India, we looked overseas and assessed that Switzerland was a high benefit proposition. Also, there is cutting edge research happening in the space of monoclonal antibodies in Europe and a lot of talent is available,â€? he elaborates. The current team comprises around 50 scientists, with expertise in molecular biology, cell biology, immunology, antibody engineering, quality control and quality assurance, process development and biologics product development. Dr. Michael Buschle, who brings with him 25 years of experience in biologics, heads the operations in the capacity of president.

Operational since 2006, Glenmark Pharmaceuticals SA has filed several patents on novel monoclonal antibodies. Lead product GBR 500, an NBE under development for treatment of multiple sclerosis (MS) and other inflammatory diseases, is undergoing phase I clinical trials in the US and GBR 600 a monoclonal anti-platelet antibody, is ready to start phase I trials in the UK. The market opportunities for both these NBEs are huge. In the MS segment, GBR 500 has a market opportunity of up to $3 billion while GBR 600 has a market opportunity of $2 billion. â€œWe have a whole pipeline of MAbs, and every year you will see one or two MAbs going into clinical trials. This is all novel antibody work and we have our own patents and IP,â€? he elaborates.

Biologics research at Glenmark Pharmaceuticals SA will look at targeting areas like oncology, immunology along with RA and various inflammatory conditions. The unit has capabilities to develop monoclonal antibodies from inception to preclinical; and undertake the necessary development work for clinical studies.

Saldanha believes that biosimilars is a big opportunity for Indian biotech companies and while he may consider entering this space in the future - he is convinced that novel biologics is the way ahead.

The Challenges

Saldanha's bold step into drug discovery space came with a host of challenges. However, he stuck to his guns. â€œBack in 2000-2004 we got a lot of flak from shareholders for investing in innovative research, because they believed that a small company like Glenmark could not deliver on innovation,â€? recalls Saldanha. It was a host of licensing deals that bolstered investor confidence. In 2004, the company signed its first licensing deal with Forest Labs for PDE4 Inhibitor, then in 2006, an outlicensing deal with Merck and in 2007, it out-licensed GRC 6211 to Eli Lilly. â€œThat gave people a stronger belief that we know how to play the game and how innovation can be done despite limited resources. By 2007, we were the darlings of the investors,â€? he adds. By then, the company's market cap touched $4 billion (18,339 crore).

In 2008, Glenmark faced major reversals. GRC 6211 was returned by Eli Lilly, Merck terminated its dealfor GRC 8200, the

Forest deal also failed. This impacted the company's stock price and its valuation adversely.

â€œThe years 2008-2009 were dry years for us, people lost confidence in Glenmark. But luckily, we had cash in hand, having spent only half of about $125 million (~550 crore) set aside for innovation. Recession in the global economy added to our challenges,â€? he reveals.

By 2010, the company bounced back strongly. The deals with Sanofi aventis and Lay Line Genomics, bolstered the investor morale; and Saldanha hopes to see more such deals. â€œWe have seen the whole cycle â€“ right from being nobody, with people doubting our capabilities to being the darlings, and then plummeting down, and then starting all over again,â€? he quips

Despite predicaments, the company's conviction and passion never wavered. â€œNothing has changed over the past 10 years. We still have the same drive and motivation to innovate. We did not doubt the way we built up the business, even in the dry period,â€? Saldanha asserts.

Nayantara Som in Mumbai