

Claris now targets biogenerics

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Having consolidated its plans in the hospital critical care market, Claris Lifesciences now intends to emulate the same in the biotechnology space.

Along with its globalization ventures and consolidation plans in the Indian critical care segment, Ahmedabad-based Claris Lifesciences, having a CAGR of 40 percent for the last five years, has now forayed into the biotechnology arena. Claris Biosciences, which was initiated in 2007, is an extension of the company's overall strategy to target niche markets and biotech was an obvious answer to this business model.

Commenting on this venture, Aditya Handa, CFO, Claris Lifesciences, explained, "Basically we did not want to get into the traditional areas as they are highly over-competitive in nature. Our strategy is to focus on our existing strengths in niche areas and at the same time give in our best to focus on those. This will eventually lead to a strong base building in knowledge, which is done by investing in manpower, training them, setting up robust capabilities and then approaching the need for innovation. This is the first phase of our business strategy and will prove to be a major differentiator for us in the market in addition to our strong distribution network."

While focusing on key therapy segments namely oncology and nephrology, the company went on retrospection on its major strengths and the opportunities that these key strengths had to offer. "We chalked out on various options and there was the obvious temptation to get into areas like lifestyle diseases, but we have tried our very best to stay from them. We came to the

conclusion that Claris has a strong hold in the hospital critical care segment and institutional customers, developing and manufacturing injectables. Biotechnology then came as an obvious answer," Handa added.

"Claris is a major player in the injectable domain and half of the injectables in the market are all biotech products. A number of these high-value biotech products are going off patent and this itself provides a huge opportunity for any company who has the capability to tap this space. Moreover in biotech, the obvious capabilities that are required are both from the technical and marketing side and both these areas have a direct link with the trend followed at Claris Lifesciences. This results straight in synergy in competency in the manufacturing front which has been our forte," stated Handa.

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With the venture kicking off, biogenerics is one of the main targets for Claris. The company's mammoth expansion ventures across the globe in the past has been an impetus for channelizing its plans towards biogenerics. "The first step would be going into biogenerics because that will be the next big thing," Handa disclosed. Collaborating with research institutes both in India and abroad will be one such strategy. Claris already has a strong global presence in the European, Central and South American, Asian, Korean and Pacific markets. This, Handa believes will take them way forward in the biogenerics market. Here, apart from entering the regulated markets of the US and Europe, Claris is also eyeing emerging markets, which it believes will eventually give the company a strong footing in biogenerics. "We have a strong base in emerging markets like Brazil, Russia, Indonesia and Mexico. Biogenerics has an interesting proposition in these regions as they are semi-regulated markets and has no immediate barriers there," Handa pointed out. While Handa believes that making a presence in the US markets might not be a cakewalk for them, finding a pathway there still remains on the cards. "The US is a potential market but we want to wait and watch how the US regulatory markets open up," Handa said. The European market is restricted only to a few companies and it is a very expensive process. The company also intends to export erythropoietin to these countries. "We are basically targeting emerging markets and then as and when the regulatory markets ease out, we will then take a call on how to penetrate the regulated markets of the US and Europe independently or partnering with somebody," he informed.

In addition to being a critical care company, therapeutic areas has always been a favorite exploration ground for Claris with its special focus on oncology and nephrology. "We have a strong base in nephrology and we recently entered oncology, which is considered the sunrise industry. We are using these two platforms to foray into biotechnology and launch our biotech products. These may be further stretched to launch other innovative products," confirmed Handa. The company also intends to foray into biopharmaceuticals as they believe that EPO and GCCF products are similar to critical care and oncology business of Claris.

Apart from this, the company also has plans up it sleeves to make its presence felt in the Rs 3,053-crore (\$745 million) vaccine market. The vaccine business alone registered 30.41 percent growth last year. Though not officially announced, the company claims that it sees a world of opportunities in this niche market, which accounts for 51 percent share of the total biopharma market. "Vaccine market is a lucrative space and going into this market will be beneficial for us as it is in line with our strength, that is the injectables market. Here we have the expertise, which means development, manufacturing, registration and also selling to large institutions," added Handa. However, even in this market, it does not want to get into avenues already explored and try other non- traditional areas. "One should also keep in mind that there are other areas in vaccines which is developing very fast. We want to get into a something which is technologically complex and hence very lucrative as a business proposition," Handa said.

Investments and plans

The company was reluctant to quantify the total monetary investments in its biotech venture. "Monetary investments is something which is intangible for us now. Four-six percent of our revenues goes to R&D and a significant part of that has been going to biotech," revealed Handa.

Investments for Claris Biosciences has been in the form of manpower and infrastructure. "Biotech investments is not just about the financial aspect but also on the acquiring the knowledge base. We have initiated the biotech activity more than one and a half years ago, fortunate to get a very good team and now we are at a phase where there will be ample lab facilities up and running so the plan keeps expanding," added Handa. Currently, the investment for Claris has been more on the time spent to understand the market in knowledge applications namely positioning an experienced team, setting up a the building to commence the biotech facilities. Starting with the short-term objectives of buying of the shelf technology wherever available, in-licensing technologies, developing non-infringing process technology, and a focus on drug molecules coming off patent, as well as product development in collaboration with other partners, in the long run Claris Biosciences intends to get into a discovery and research led growth strategy.

As far as long term plans are concerned, biotechnology will be used as a platform to foray into other related areas like

vaccines – plans for which are still in its preliminary stages. Similarly, in oncology there would be an innovative platform as such combining biotech with other niche areas. "We are evaluating those platforms. However, since we do not have a global strategy, we have not declared the model though we have started work on some of them," Handa disclosed.

The company has divided its investment plans into three phases. The first is the setting up of the lab facilities and getting the product level and the next phase would be setting up the manufacturing front and the third phase would be commercially producing the biotech product. Stage two, which is product manufacturing would again be divided into two phases. The first phase being the GcMP pilot plan and the next phase, which would be a much later stage would be to set up a full-fledged plant.

Eventually the ultimate target of the company would be investing in the R&D space. "That would be the logical step for any company getting into the biotech space. However, as of now, we are aware of our limitations since we have just got into this space," added Handa. The company is being realistic and focusing their plans and thought processes on their first phase of the investment.

As far as investing in human resources is concerned, Claris Biosciences is tapping young talent. At present the employee strength is 20 but the target is to recruit another 20-25 personnel in the coming year. "We take in freshers, train them in reputed institutes depending on the kind of training that they need and fit them into our own strategy. We also train our own people and that is the best way to retain them," said Dr Gita Sharma, head-biotech, Claris Lifesciences.

Targets in the coming year

Monetary targets are not Claris has on its cards as it believes it is not the right approach. "We strongly believe that we are in the investment phase currently and this investment phase is a good 3-5 years. So we want to build a solid base in terms of building the capability of the company. We depend strongly on our development programs and do not happen to keep our eyes on numbers. That will happen in due course of time the focus is now on development programs and keep investing in our building capabilities," Handa said. As of now the main focus is on the initial products that they have taken, register them as soon as possible and begin sales in emerging markets by 2009-2010.

Handa does not rule out the possibility of alliances in this venture though at this stage he is tightlipped about the issue. "It is a strong possibility. Biotech is a knowledge intensive space and it does not make sense to build a knowledge base on your own if you have to spend that amount of time There should be an alliance in the near future," he added.

Lab facilities

In line with its vision for this segment, Claris has invested in a state-of-the-art biotech laboratory, equipped for development of biosimilars, development of novel biologics, facilitation for technology transfer, biotherapeutic protein drug testing and characterization as per the US, European and British Pharmacopoeia and co-development for biotherapeutics. The company's biosciences manufacturing facility is being designed to include facilities for API manufacturing using both microbial and mammalian cell lines, for products such as Erythropoietin, G-CSF, Interferon and others, along with formulation and filling facility for finished biotherapeutic protein drugs, both in vials and PFS.

"We can do all tests under our roof. We have a state-of-the-art molecular biology laboratory, a stem culture lab, a small GMP lab and everything connected to R&D. We are also putting up a state-of-the-art animal facility, we have the facilities for protein batch release, characterization and identification," added Dr Sharma.

With these myriad targets in the biotech space and having had a decent share in the Indian market, Claris Biosciences intends to amalgamate its current strengths and therefore find success in their biotech venture.

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