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â??Treading on the COVID-19 vaccine opportunity undoubtedly has added a new dimension to our capabilitiesâ?•

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Shilpa Medicare Limited (SML) started its operations as API manufacturer way back in 1987 at Raichur, Karnataka. The commercial production in the SML was started in November 1989. Today SML, with a consolidated revenue of R 1,159.76 crore for the year 2021-22 against the previous yearsâ?? revenue of Rs 931.27 crore, has emerged as a global brand within manufacturing and supplying of affordable API and Formulation globally in different regulated markets. The Group with over 20 subsidiaries is now setting up a greenfield project located in Karnataka. BioSpectrum India spoke to Vishnukant Bhutada, Managing Director, Shilpa Medicare Limited on the new facility and challenges and growth of the company. Edited excerpts;



Shilpa Group is setting up SBPL, a greenfield project located in Kadechur industrial area space spread across 30 acres in Karnataka. How much is your investment in this project?

Shilpa Group started in 1989 with the vision of becoming a pioneer in niche areas of pharmaceuticals. We started with Oncology API's followed by finished dosage forms and eventually evolved with diversified areas including Therapeutic peptides, speciality polymers, advanced intermediates, finished formulations (Injectables, Oral solids, Transdermal patches, Opthalmics, Oral thin films), Biologicals and Biosimilars.

With 3200 plus employees, 492+ patents filed, 200+ DMF filings and several international regulatory approvals, listed in NSE, BSE, I always felt that something more needs to be done.

It is with this thought that we set up Shilpa Biologicals at Dharwad, Karnataka to achieve a prominent position in Biopharmaceuticals space with our own pipeline of Biosimilars, New Biological Entity and CDMO services from our world class facilities.

Shilpa Biocare, the new site at Kadechur, Karnataka was envisioned even before the pandemic to have a world-class large scale facility for manufacturing of fermentation based API and therapeutic products on Microbial platform (preferably E.coli and Pichia pastoris) to avoid dependency on imports. Now this project is of high relevance in the context of a pandemic situation where there was shortage of such products with high dependency on imports especially from China. Our new project at Kadechur is in line with our government's vision of Atma Nirbhar Bharat. The investment is to the tune of Rs 400 crore.

Are you looking to raise additional funds for this project?

At this stage we haven't made a concrete decision on this although we have been approached by financial institutions and likeminded companies. Now that the project is in an advanced stage there are various opportunities that are being evaluated in addition to manufacturing of our own NBE-Recombinant Human Albumin.

When is it expected to be completed and become operational? How many jobs will it create? Any particular reason to set up in Kadechur.

The project is expected to be completed by Q4-2023 and it will create about 400 jobs.

As a company we always “Think global but actLocal”. We had set up our first manufacturing site in Raichur (200 kms from Hyderabad) but successfully managed to get our facilities audited by several international agencies including USFDA, EU, PMDA-Japan etc. and registered our products in international markets much to the satisfaction of our customers and shareholders. In this process we created huge employment opportunities for many locals.

Likewise Shilpa Biologicals (for our Biological Drug substance and Drug product site in Dharwad) we were aiming at a location in Karnataka.

Shilpa Biocare location at Kadechur was also to set up a facility in Karnataka at a location other than Bangalore and in the process create local employment opportunities.

Although we are located in Karnataka with manufacturing sites in Raichur, Dharwad, Dabaspet, we have our R&D centre at Raichur, Bangalore, Ahmedabad and Dharwad and offices in Mumbai, US, Europe and employees from pan India.

To summarise we had this firm belief that if we have a clear vision, right commitment and business principles laced with “Quality in Mind” we can always make our presence felt irrespective of location.

Could you give us some insight about your Biopharmaceutical SBU - Shilpa Biologicals?

Shilpa Biologicals started with a vision to provide quality, affordable, accessible Biopharmaceutical healthcare products to patients across the globe.

While in the pharmaceuticals space we have achieved excellence and continue to improve our products and services, we wanted to embark on a similar path for Biopharmaceuticals.

Shilpa Biologicals is the biological site where we have a full range of capabilities right from “Concept to commercialisation”.

We have a unique Business model which is “Self-propelled and Synergistic”. While we develop, manufacture, register and commercialise our own Biosimilars and NBE, we are also a prominent CDMO (Contract Development and Manufacturing Organisation).

Our Biosimilar pipeline includes high concentration Adalimumab (ORIADALI), Aflibercept, Abatacept, Tenectaplase, Pembrolizumab and New Biological Entity- “Recombinant Human Albumin'' which is developed for both Therapeutic and Non-therapeutic applications. We are the first company in India to develop and successfully complete Phase-III study of high concentrated biosimilar Adalimumab. Soon to be commercialised in India.

Our CDMO model from a very early stage has started providing services to various clients- Sputnik-V for and DNA Vaccine for COVID-19 vaccines have been manufactured by us.

We have a world class Infrastructure:

- Our R&D has capability of Clone development, Process development, Analytical development and full product characterisation.
- We have dedicated drug substance manufacturing facilities for microbial and mammalian based products and three drug product facilities for filling in PFS and Vials. Our highspeed vial line with high throughput has been specifically set up for high volume products especially vaccines.

In addition to above through our new division ‘Shilpa Biosciences”- domestic marketing division we will improve the reach of our high-end biologicals pan India directly and through government institutions including but not limited to “Pradhan Mantri Janaushadi Pariyojana”. We are also in discussion with several domestic companies and multinationals to in-license biological drugs to improve the access of lifesaving drugs.

How is this new facility different from other facilities?

We are setting up about 250 KL large scale fermentation facilities which, presently, we don't have in any of our current facilities.

Each facility of ours is different:

1. API Facilities at Raichur, Karnataka
2. Oncology Formulation unit at Jadcherla, Telangana
3. Film/TD Formulation unit at Dabaspet, Bangalore
4. Biological unit at Dharwad, Karnataka
5. Fermentation facility at Kadechur, Karnataka

Differentiation of Shilpa Biocare (new site at Kadechur) stems from our vision to have a large scale world class facility for manufacturing of fermentation-based products with equally sized downstream facility for purification of therapeutic proteins. The uniqueness is in the infrastructure that allows manufacturing of multiple products including but not limited to "Recombinant Human Albumin", Recombinant Human Insulin and analogs, Recombinant Enzymes etc. In addition to this we have earmarked adequate space considering the need for expansion in near future.

Can you give us some insight on how your current biopharma facility and the upcoming one will bring overall growth to the group?

Shilpa Biologicals will set the launch pad for its growth with the commercialisation of Adalimumab (ORIADLI) in India. This will be followed with other biosimilars that will set the tone for overall organisation growth driven by improving the outreach of these biosimilars to patients across the globe. Our US and EU strategy is well crafted and can by itself change the entire landscape. Our distinctive CDMO services will also play a major role in this growth path.

Shilpa Biocare is again on the lines of Shilpa Biologicals – "Self-propelled and Synergistic". Our NBE by itself is a blockbuster product. While it has the potential to garner a major share from the ~$6 billion market, our flexibility with the CDMO model will aid in self progress.

Biopharmaceuticals/biologicals are a slow growth but profitable business in the long run. Patience always brings promising results.

Hence these two businesses in due course of time will definitely bring in overall growth of Shilpa group.

Manufacturing of COVID-19 vaccines has not been a commercial success but you've, nonetheless, developed the capabilities of Recombinant vaccine manufacturing. What was the major learning from this?

It was a good learning. But we must be careful in the future while investing in new areas.

Treading on the COVID-19 vaccine opportunity undoubtedly has added a new dimension to our capabilities enhancing our manufacturing capacities that will be put to full use for Mabs business in near future.

Our intent was primarily to rise to the national demand for vaccine security and hence it was a conscious decision to venture into this. Unfortunate situations resulting from unprecedented market dynamics which were beyond anybody control, we missed the opportunity.

Although it has been a setback from a financial angle there has been more pros than cons. With the vaccine experience, we are now being approached by a few multinationals for CDMO services.

You have a list of over 20 companies as subsidiaries, joint ventures, which ones are giving good growth and how do you see the growth for these firms in the post pandemic era?

Globally most of the companies of our size are ideally looking to consolidate their position depending on the degree of setbacks owing to the market situation and naturally a moderate progress is expected.

Having said that on the small molecules front we are working to develop new products which are set to launch by next 2-3 years. Similarly our Therapeutic peptide division is also developing a good pipeline of products some of which are going off patent in next 2-5yrs.

Shilpa Biologicals (Biopharma Business), Shilpa Biocare (large scale facility) and Shilpa Biosciences (Domestic marketing division) as mentioned earlier are expected to further elevate our position in domestic and international markets.

We are reenergised in our quest for growth post pandemic era notwithstanding the moderate progress.

What are the current challenges before the company?

The main challenge is in monetising the investments made in the last few years which didn't progress as expected due to the unprecedented pandemic situation. This, apart from the dynamics in the regulatory environment due to lack of convergence in systems across various countries, are main challenges.

Nevertheless, since our Biosimilar Development programme has been built in accordance with EU/US standards on the basis of "Totality of Evidence" we expect that we will be able to open up many markets that will have access to our Biosimilars in the next few years thereby resulting in good progress overall.

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