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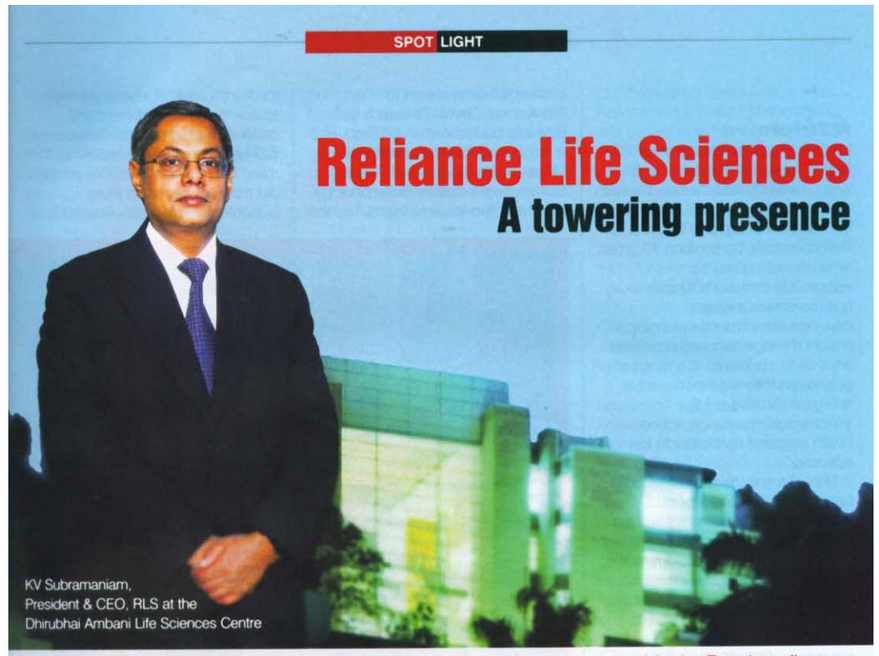

KV Subramaniam,
President & CEO, RLS at the
Dhirubhai Ambani Life Sciences Centre

As Reliance Life Sciences nears the close of its first decade of existence, Viveka Roychowdhury does a status check on this market leader

As India's largest private sector enterprise, the Reliance Group straddles sectors as varied as textiles to petrochemicals and since 2002, life sciences. With annual revenues in excess of $ 30 billion, vertical backward integration has been the strategic game plan of the Group which has seen it gain not just domestic but also global dominance in the sectors were it is present.

Which was why its turn-of-the millennium foray into life sciences was met with some skepticism. This was not a logical backward integration. But the logic was very simple. Very ironically, the Group's think-tank was deliberating on what sectors and products could undermine its leadership presence in fossil fuel-based industries like petroleum, petrochemicals, oil and gas. Bio-fuels was being seen as an alternative to fossil fuels and the Group started to consider how big a threat this could be to their flagship company, Reliance Industries Limited (RIL). This exploration led to the domain of Industrial Biotechnology and consequently, an understanding of the potential that the field of biotechnology held. The vast opportunities in medical and plant biotechnology then came to light. This led to the conception of the Life Sciences business, which is completely different from the traditional business of RIL in terms of the scale of operations, business model, commodities, technology licensing and so on.

The Group then decided to turn this potential threat into an opportunity and Reliance Life Sciences (RLS), incorporated in 2001, became an epitome of the new millennium initiative of the Reliance Group. RLS started activities in 2002 operating out of H N Hospital, Mumbai. In 2005, RLS moved to its headquarters to the Dhirubhai Ambani Life Sciences Centre (DALC) in Navi Mumbai. Today, RLS is a research-driven, biotechnology-led, life sciences organisation participating in medical, plant and industrial biotechnology opportunities. Specifically, these relate to Biopharmaceuticals, Pharmaceuticals, Clinical Research Services, Regenerative Medicine, Molecular Medicine, Novel Therapeutics, Biofuels, Plant Biotechnology and Industrial Biotechnology.

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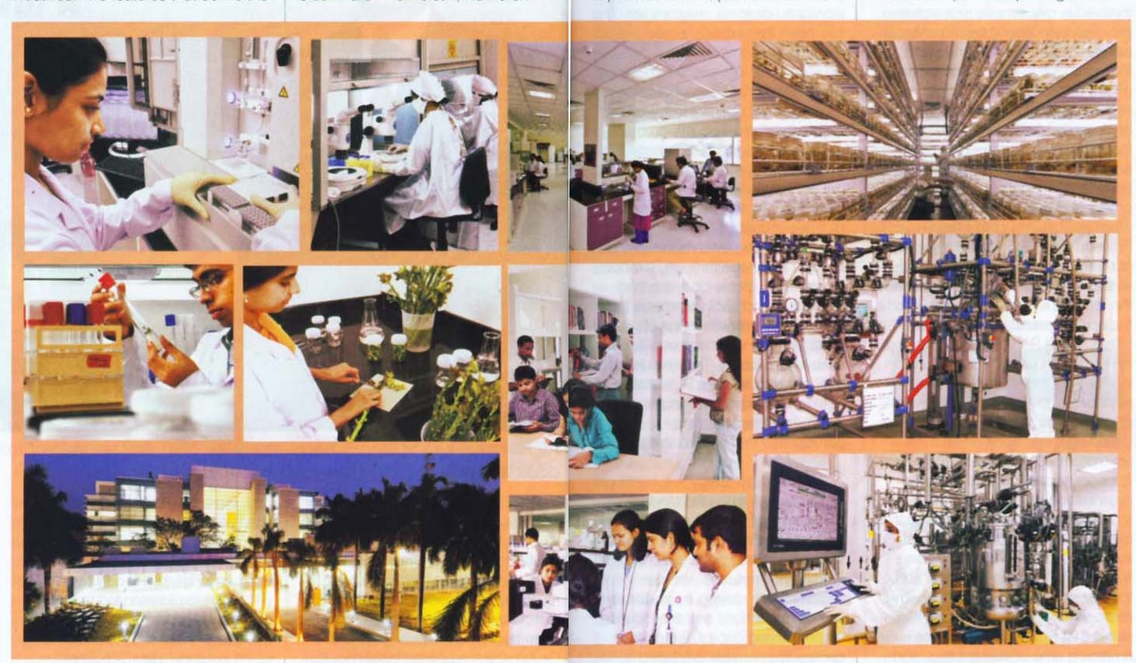
At the helm

KV Subramaniam, President & CEO, RLS, a veteran of the Reliance Group, was chosen to head the new venture. In a career spanning 28 years with the Reliance Group and Indian Petrochemicals Corporation, KVS (as he is referred to) has been responsible for several functions - from corporate business development, corporate planning, project management and economic analysis to marketing; in a range of businesses - from petrochemicals, energy, alternative energy, infrastructure, insurance, education, health care and agriculture to life sciences.

Recollecting the planning stages, he says, "There were a lot of imponderables at that point and we looked at four things broadly - issues related to science, technology, scale up and economics. The infrastructure was built and talent was brought in with a research focus for development of products and services in different areas. We realised that when novel research in areas such as Therapeutic Proteins, Plant Tissue Culture, Stem Cells is pursued, the pathway is very long and has to be balanced with other areas. This led us to focus on areas such as Molecular Medicine, Clinical Research and Biosimilars, as stepping stones to get into novel areas of research." This approach ensured that within the first few years itself, RLS had operational revenue streams, which meant that it could plough back this revenue into new ventures, and did not need to go back to the parent company for capital, other than the start-up funds.

Eight years down the line, KVS says that RLS is financially at break-even stage. Operationally, the company is at a scale-up phase and has developed a reasonable understanding of issues related to science, technology, scale up and economics with respect to Biopharma, Clinical Research and BioFuels businesses. In addition, RLS is incubating Regenerative Medicine, Molecular Medicine, Plant Tissue Culture, and Industrial Biotechnology initiatives. Two features that define the RLS business model, KVS emphasises, are that the technologies are all internally developed and the tremendous broad-based play. Very few life sciences organisations in the world have such a diversity and integration between the life sciences businesses as diverse as stem cell technology and bio-fuels.



Threat turns to opportunity

RLS is now at a stage that will see the fructification of several years of research and development and capacity building efforts. Several products and services are being rolled out. Listing them, KVS points out that RLS launched three biosimilars - ReliPoietin, ReliFeron and ReliGrast in the market, the first commercial stem cell therapy ReliNethra; a pharma oncology product (Temozolomide), an umbilical cord banking service, several molecular medicine test services and biodiesel in 2008.

RLS is gearing to launch three more biosimilars, two stem cell therapies and several pharma products for the generics space. KVS states that they have the deepest biosimilar pipeline in the industry. RLS continues to develop a range of products and services in the biopharmaceutical, pharmaceutical, regenerative medicine and molecular medicine domains, many of which are in clinical trials.

The heart of RLS

The flagship facility is DALC in Navi Mumbai, spread over 20 acres, and housed in the futuristically-styled environmentally friendly structure (seen in the background in the cover visual). The building makes optimum use of natural light and is in fact like a huge greenhouse, with many plants from the Group's tissue culture labs lending a soothing green touch to the corridors. The Group has a thriving exclusive contract production business, of ornamental plants as well as production and research in horticulture (banana, pomegranate and potato), floriculture and ornamental, plantation and medicinal and aromatic plant species.

DALC is among the most diverse and integrated life sciences campuses in the world. Its diversity stems from the wide spectrum of areas of R&D undertaken and its integration comes from repository, laboratory research, pre-clinical research, clinical research and manufacturing facilities; all located in the same campus.

The second facility is in Bangalore, for clinical pharmacology and clinical data management. RLS also has a pilot facility for manufacture of clinical lots and initial market introduction of Plasma Proteins and Recombinant Therapeutic Proteins in Mumbai, a facility for commercial scale manufacture of Plasma Proteins at DALC, Navi Mumbai and R&D farms in Kakinada, Nagothane and Gandhar to develop composite varieties of Jatropha for the bio-fuel venture.

In the recent past, RLS has completed a fill-finish facility for commercial scale recombinant proteins manufacture, a larger Plasma Protein manufacturing facility, a kiloscale API facility and a biodiesel manufacturing facility. The recombinant facility is India's largest, and has suites both for mammalian cell culture and microbial fermentation. RLS also offers contract biopharmaceutical manufacturing services.

Chosen focus areas

KVS sums up RLS' biopharma initiative listing its focus areas: developing biosimilars, monoclonal antibodies, fusion proteins and SiRNA molecules. The Pharma initiative is focused at API and formulation in oncology segment, steroids, peptide and hormones. The Clinical Research Services initiative offers services in the domains of Pre-clinical Animal Studies, Phase I Studies, Phase II to IV Studies, Bioavailability and Bioequivalence Studies, Clinical Data Management, Biostatistics, Clinical Trial Supplies Management, Medical Writing, Pharmacovigilance, Regulatory Services, Quality Assurance in clinical trials and Cardiac Safety Studies.

The Group's slightly late entry into the BioFuels industry has in fact allowed it to learn from the mistakes

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of the early birds. RLS BioFuels initiative is uniquely integrated and is unparalleled in the world because it incorporates principles based on using marginal land and staying away from fertile land used for food crops; working with marginal farmers to help improve quality of rural livelihoods and incomes; promoting multi-culture agronomy and building a business that is robust to low prices of crude oil. The components of the biofuels initiative include Agronomy, Farm Advocacy, Plant Tissue Culture, Plant Metabolic Engineering, Trans-esterification, Enzymology and Industrial Biotechnology. This effectively forestalls critics who tout the food-for-fuel argument to justify the stance that biofuel crops will eat into the food crop area and result in food shortages and famines.

Research leads

With respect to Regenerative Medicine, the focus is on translational work with the objective of developing therapies or tissue engineered products. RLS is working on six therapies in areas of cardiology, ophthalmology and dermatology. In the area of Molecular Medicine, Reliance Life Sciences is involved in: DNA/RNA based high-end diagnostics, Molecular Genetics and Predictive Diagnostics. Reliance Life Sciences provides DNA/RNA based diagnostics services for infectious diseases, qualitative tests for detection and quantitative assessment of the viral/bacterial load of infectious agents, including HIV and associated organisms like HCV, HBV, TB and CMV, using PCR, PCR-Sequencing (for genotyping) and Real Time PCR for precise quantification of viral and bacterial load, as also for expression analysis.

RLS has ongoing research programmes on Genotype-phenotype correlations in several cancers of significance in the Indian context, including Oral Cancer, Breast Cancer, Cervical Cancer and Colon Cancer, with the ultimate goal of developing predictive markers in human cancers and understanding their molecular pathology. In the area of Molecular Genetics, RLS is involved in cytogenetic research and provides cytogenetic testing services using modified Karyotyping and Fluorescence In-Situ Hybridisation (FISH) based assays to detect numerical and structural chromosomal abnormalities, including translocations, amplifications and micro-deletions in peripheral blood cells, bone marrow, products of conception, chorionic villi, amniotic fluid and cord blood. Prenatal diagnosis for all karyotypic aberrations and rapid FISH based assays for Down's Syndrome add to the repertoire of essential high-end molecular genetic testing services offered by RLS. RLS is also involved in Predictive Diagnostics research in the field of Oncology, with the objective of predicting increased risk of developing a disease in the future based on a test done on an asymptomatic person (person who appears normal). RLS is the only organisation doing BRCA 1/ BRCA 2 mutations testing for familial breast cancer in India. RLS uses state-of-the-art technology i.e. DNA sequencing - 'a gold standard' and the test shows 100 percent sensitivity and specificity. Going forward, KVS states that RLS will focus on the emerging area of Theranostics and work with pharma companies by providing diagnostics services that can support therapies for areas such as HPV etc.

The decade ahead

KVS says the greatest challenge to the Group's plans has been competency development. Typically, Group decided to find the solution in-house and to meet this requirement, Reliance Institute of Life Sciences (RILS), a not-for-profit organisation was set up, focusing on competency development in biotechnology, not only for Reliance Life Sciences but also for the industry. RILS offers competency development programmes through the young professional programmes and advanced diploma programmes. This has been the institutionalised response to competency development. The second challenge, according to KVS, is globalisation. KVS says that they will focus on registering their products in other countries. Reliance GeneMedix plc, an Ireland-based subsidiary of RLS will be involved in marketing biosimilars for the European market. RLS is conducting clinical trials for two biosimilars - Erythropoietin and GCSF - in Europe through Reliance GeneMedix. Scale-up is the third challenge, and KVS comments that RLS will have a wide range of products and services that will sustain profitability. The next decade, KVS predicts, will see RLS scaling up, getting new products in novel areas into the market and more participation in global markets.

Slowdown strategy

Commenting on the slowdown, KVS says that biotech start-ups are increasingly finding that the value of their holding has gone down and funding has reduced. Venture capitalists are staying away due to lack of exit options and are focusing on conserving capital. Big pharma companies are less interested in acquiring smaller biotech companies. Healthcare in developed markets has suffered due to prescriptions not getting filled and people opting to delay procedures.

As for RLS, KVS says that they are focusing on strong profitability this year and shifting from a build to consolidation mode. The focus is on improving productivity across all fronts - capital, manpower and R&D. ■

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