



GLOBAL BUSINESS REPORTS



INDUSTRY EXPLORATIONS

INDIA PHARMACEUTICALS 2015



*Manufacturing | Regulatory Framework | Patents | Foreign Direct Investment | Export
Biotechnology | Ayurveda | Contract Manufacturing | Research and Development*

Arjun Handa

Managing Director and CEO
CLARIS LIFESCIENCES LTD.



Claris is one of the major producers of injectable pharmaceuticals. Could you provide us with some information about the company's background?

Claris was initially established to cater to the injectables segment. We produce finished formulation injectables in the fields of anesthesia, nutrition and infusions. At the time of the company's founding, we felt that there was a gap in the Indian market for a high quality, affordable injectables manufacturer. Historically, Indian manufacturers tended to focus on the production of older molecules and compete primarily on price. From the outset, we wanted to deliver newer molecules that better addressed the needs of patients. We started off with the production of propofol, which is now the most popular anesthetic on the market and offers patients a much faster post-operation recovery time. We also offer a range of amino acids and lipids that can cut down this time, thus reducing bed usage and healthcare bills.

What would you say are the main values behind Claris' corporate philosophy?

Our primary concern is quality. Injectables are difficult to manufacture and, as the product is going directly into the bloodstream, there is no margin for error. Unlike orally administered drugs, injections bypass the body's immune system. All of our plants are world class and numerous inspections, including from the U.S. FDA, have confirmed this. After quality, affordability and accessibility are our driving forces. To ensure that our products reach as many patients as possible, we operate a large distribution network, with close to 1,000 outlets stocking our products across India. On a global scale, we export to 95 countries and work with 100 distributors.

Claris is involved with several joint

ventures with Japanese companies such as Mitsui and Otsuka. How difficult has it been to enter the Japanese market?

To clarify, the Claris Group is divided into two separate companies: Claris Injectables and Claris Otsuka. Claris Otsuka works with relatively common-place infusions, such as dextrose or saline. Although these are produced in joint venture with the Japanese company, Otsuka, they are sold in India and other emerging markets. Claris Injectables produces generic injectable molecules that are mostly exported to the United States and Europe. In terms of revenue, both companies contribute approximately the same amount. We have not yet attempted to move in Japan. It offers great potential but is difficult because of its strict demands on packaging and quality. It is necessary to have a strong local partner. The joint venture is more about bringing Japanese products to India than exporting Indian products to Japan.

What strategies are you adopting to develop Claris' business in the medium-term?

Our main strategy is to broaden our product offering; over the next three years we plan to roll out 48 new products on a global level. Our research and development (R&D) department is constantly looking to develop new generic formulations. We prefer to develop products that are not widely manufactured. We do not research new molecules but work on new ways to deliver our products. Within injectables there are many associated technologies: suspensions, emulsions, powders, pre-filled syringes, which we always try to make more efficient. Claris is currently the only company in India to deliver drugs in bags, rather than the typical bottle or vial. This has the advantage of being far easier to sterilize.

The Claris Group recently inaugurated

its fifth manufacturing facility, which will help boost total production capacity. We have many products filed in the United States and Europe, as western countries are looking to bring down healthcare costs. We are already present in the main healthcare markets, but in the case of infusions and other more affordable products we are targeting new opportunities in Africa, Latin America, and the CIS countries.

What factors do you believe have led to Gujarat's dominant position in India's pharmaceutical production landscape?

There are several reasons for Gujarat becoming a pharmaceutical and industrial hub. It offers quality infrastructure, surplus power, and abundant skilled labor with a low level of unionization. Government policy is very industry-friendly, it is relatively easy to set up a new business, and bureaucracy is not as onerous as in other states. Of course, there is room for improvement. A discharge network to take care of plant effluent would be a great boost. This is already present in various industrial clusters but on a regional level these individual treatment plants do not link up.

Where do you hope to see Claris in five years?

If all goes to plan, we will be an important player in regulated markets, particularly in the United States. Because of the breadth of our product portfolio we could become a key supplier to new markets. As for the infusions business, we plan to expand to reach an even greater number of patients in emerging markets. We hope to move into more production of general injectables that will cover a larger range of therapeutic segments. Anesthesia and renal treatments will continue to be our main drivers but there is potential to broaden our portfolio to other areas such as pain management. •

Claris Lifesciences Ltd.

MANUFACTURING AND RESEARCH AND DEVELOPMENT (R&D) FACILITIES

ISO 9001-2000 and WHO GMP certified

THE STATE-OF-THE-ART LABORATORY SET-UP

World-class machines, including: DRO from Christ, Switzerland WFI from Stilmas, Italy Vessel from Diesel, Germany Bomer (Bag Printing Machine), Germany Bosch (Ampoule washing Machine), Germany

REGULATORY APPROVALS

United States, United Kingdom, European Union, Australia, New Zealand, Gulf Cooperation Council, Brazil, Columbia, Tanzania, Uganda, Oman, Ethiopia, Egypt, India

QUALITY PHILOSOPHY

Commitment to achieve a level of perfection that matches the highest international pharmacopoeial standards.

Our final test for quality is a very simple question that we ask ourselves without fail: "Would we use it to treat our dearest ones?" If the answer is an unhesitant "Yes," then the product has passed our final quality test. We call this "Emotional Pharmacopoeia."

AWARDS:

- Claris Inc. in India Innovation Top-100 List (2013)
- Merit Award (2011)
- Best Supplier Award (2010)
- Greentech HR Excellence Award (2010)
- IMEA Award (2009)
- IDMA Quality Excellence Award (2009)
- India's Best Company to Work Award (2010-2013)

KEY PRODUCTS IN THE UNITED STATES

Source: Claris

MOLECULE	ANDAS	GLASS VIALS	BAGS
Ciprofloxacin	2	YES	YES
Fluconazole	3	YES	YES
Furosemide	1	YES	
Levofloxacin	2	YES	YES
Metoprolol	1	YES	
Metronidazole	1		YES
Norepinephrine	1	YES	
Ondansetron	2	YES	
Total	13		