



Progenerics Pharma Pvt Ltd



Global Pharmaceutical industry overview

The global generic drug market was valued at nearly \$432 billion in 2017 registering a compound annual growth rate (CAGR) of 11%

US is the largest generics market and accounts for 45% of global generic market in terms of revenue

In terms of revenue, US market scores with 86% of volume penetration. Key factors that will likely drive generic Industry growth are..... the expected increase in healthcare spending - \$4.5 trillion by 2020 and the implementation of affordable Care Act

A combination of strong chemistry skills, regulatory capabilities and quality manufacturing has positioned India favorably to capitalize on the global pharmaceutical opportunity



Progenerics - *The name to reckon with.... its our endeavor to establish our company as a developer of niche generic products and eventually as a contract manufacturing service provider*

An ideal destination for commitment, quality, flexible pricing models and experienced team players

Our Mission

To Emerge as successful research-based global generic pharmaceutical company contributing towards better health care

Vision

Strategic partnerships are Key to success and we endeavor to work with high quality companies focused on establishing alliances as well as to develop new product ideas in generics

Management Team



Rajashekar Rao is the Managing Director of the company. An intellect Rao is a post graduate in Engineering (M. Tech) has grown up the ranks in his career in a short period of time and turned entrepreneur with a zeal to make his presence in the Pharma industry.

Srikanth Gurram is the Promoter Director of the company. A Post graduate in Pharmacy (M. Pharm) and an MBA holder has prowess experience in reputed Pharma companies like Nicholas Piramal, Gland Pharma, Indoco Remedies and MSN Labs and served in various roles and responsibilities, specifically in Business Development and brings in a lot of experience in generic licensing agreements

Dr.Sreekanth Joginapally is the Promoter Director of the company. A Post doctorate in Pharmacy (PhD) has vast experience in reputed Pharma companies like Strides, Orchids, Natco and MSN and brings in a lot of experience in developing many a products and has experience of developing close to 70 ANDAs including First to file products and other products developed globally



R&D Site

The Site is located at Export Promotion Industrial Park, Hyderabad

*It's a green field project spread across 2.5 acres of lush green site.
The area of R&D is about **21000 sq. ft. which includes development labs and Analytical labs***

Dedicated GLP labs for both oncology and general products

Capable of Developing Oncology Solids & Injectables, general Solids & Injectables, Creams and ointments, liquids ophthalmic and potent products including hormones



Product Development Scope

Nature of Project Component

High-level activities of Project Component

Administrative

Test license, Import license in case of imported API, etc.

Formulation

Procurement of excipients, Preformulation, Packaging materials, and completion of Preformulation and Prototype development including preliminary packaging selection.

Analytical

Lab-scale Stability, Process Optimization, Packaging material optimization

Analytical reagents, working standards, impurities, columns, etc.

Method Development & Validation

Analysis of Preformulation samples

Lab-scale and process optimization batches analysis

Scale-up batches

Pharmaceutical-Equivalence

Documentation for submission



Development Stages

S. No.	Activity	Outcome Reports
1	<i>Licenses</i>	<i>Copy of certificates issued by necessary authorities.</i>
2	<i>API and Excipient sourcing & qualification</i>	<i>Vendor finalization & generation of necessary Certificate of Analysis</i>
3	<i>Reference product analysis</i>	<i>Evaluation of reference product quality attributes and generation of Certificate of Analysis</i>
4	<i>Pre-formulation & Compatibility study</i>	<i>Screening out compatible excipients and generation of report with necessary data / chromatograms</i>
5	<i>Formulation Development</i>	<i>Trials to finalize batch composition</i>
6	<i>Method development</i>	<i>Method development documents.</i>
7	<i>Stability Study for lab batches</i>	<i>Stability study report</i>
8	<i>Process optimization / Scale up/ Validations</i>	<i>Process optimization / Scale up report/Validation report</i>
9	<i>Tech Transfer Documents</i>	<i>Necessary documents to transfer the product.</i>

S.No	Development Stage	Timelines
1	<i>Innovator Sample evaluation & Pre-formulation</i>	<i>1 to 2 months</i>
2	<i>Lab Scale and Process development Studies</i>	<i>2 to 4 months</i>
3	<i>Process optimization and Pharmaceutical-Equivalence</i>	<i>1 to 2 months</i>
4	<i>Accelerated Stability Studies (for 3months)</i>	<i>3 to 4 months</i>
5	<i>Technology Transfer to Manufacturing Site</i>	<i>1 month</i>
	Total Development Time	<i>12 months</i>



BUSINESS MODELS

Developing the generic products including complex products

Assist the customer in Contract manufacturing Activities

Co-Development with target clients

Assist customer in Tech Transfer projects







Safe Harbour

Disclaimer

Materials and information provided during this presentation may contain 'forward-looking statements'. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.

The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

