

Helping people lead **healthier lives**



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# A Global Pharmaceutical Company with

- ❖ Revenue > USD 1.25 billion
- ❖ Direct presence in over 35 countries worldwide
- ❖ Operations in over 115 countries
- ❖ Workforce of >9000 employees
- ❖ 13 Manufacturing facilities (8 US FDA inspected) in API & formulations

## Custom Pharmaceutical Services:

- ❖ Integrated services comprising discovery chemistry, process R&D, API and finished dosages manufacturing
- ❖ >50 innovator customers globally including several big pharma companies

# Expertise in Biopharmaceuticals

## Marketed Products:

**grafeel** - filgrastim

**Reditux** - rituximab

## Infrastructure

- ❖ cGMP *E.Coli* manufacturing
- ❖ cGMP mammalian cell-culture manufacturing
- ❖ Fill-finish with lyophilizer
- ❖ R&D center
- ❖ Animal facility

## Pipeline:

**2** products in/near clinical development

**6** products in pre-clinical development



# Mammalian Cell-Culture Manufacturing - Current Capability



## Facility

- ❖ In accordance with cGMP guidelines; approved by multiple regulatory agencies
- ❖ Has the ability to handle most mammalian expression platforms; currently dealing only with products based on CHO cell expression

## Overall Capacity:

- ❖ 800 L : 4 X 200 L bioreactor
- ❖ One downstream processing train

## Ongoing expansion

- ❖ 600 L: 3 X 200 L bioreactor
- ❖ One downstream processing train

Expected to be operational by November 2008

## An integrated Fill-Finish facility

Equipped to handle vials (liquid and lyophilized) and pre-filled syringes

- ❖ Vials: 4 million annually (expandable to 7 million) ; Volumes: 1 to 50 ml
- ❖ Pre-filled Syringes: 3 million annually (expandable to 6 million)
- ❖ Lyophilizer: 7 sq meters

# Large Scale Mammalian Cell-Culture Manufacturing

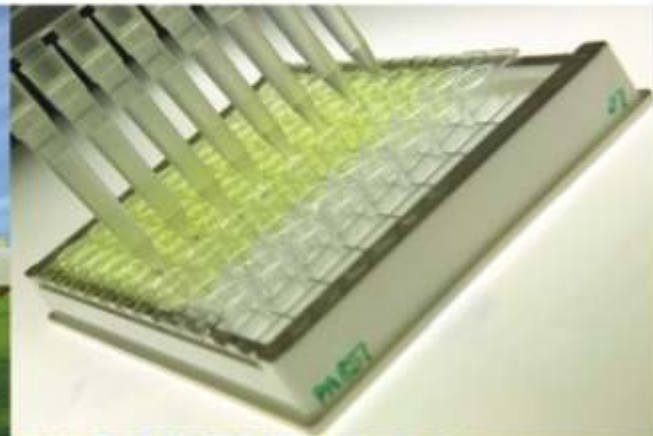
## Phase I- Expected to be operational by 2010

Facility designed :

- ❖ To comply with global regulatory norms: USFDA, EMEA and MHLW
- ❖ To operate at dual working volumes (2500L & 5000L)
- ❖ With a capacity of 15,000 L - 3 X 5000 L bioreactor
- ❖ One downstream processing line comprising clarification, capture, pre-viral purification & post-viral purification & bulk formulations

## Phase II: Post 2010

- ❖ Further enhancement in capacity by installation of 10,000 L bioreactor



### Capability

- ❖ System and expertise in developing biological products of varied complexity
- ❖ Proven skills in technology transfer, analytical development and scale-up
- ❖ Expertise in regulatory support and filing across key geographies

### People

- ❖ Team of 250 with 35 PhDs comprising scientists with significant experience in big biotech/pharmaceutical companies in US/EU
- ❖ Extensive in-house training programs