

## Safe Harbour

Except for the historical information contained herein, statements in this presentation and the subsequent discussions, which include words or phrases such as "will", "aim", "will likely result", "would", "believe", "may", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "contemplate", seek to", "future", "objective", "goal", "likely", "project", "should", "potential", "will pursue", and similar expressions of such expressions may constitute "forwardlooking statements". These forward looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to our ability to successfully implement our strategy, our growth and expansion plans, obtain regulatory approvals, our provisioning policies, technological changes, investment and business income, cash flow projections, our exposure to market risks as well as other risks. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.



# **Business Overview**

# **Company Overview**



## Legacy

35+ years in pharma with robust quality systems, regulatory and compliance framework

Generic Drugs
Substance(GDS) &
Custom Manufacturing
Solutions(CMS)



#### Scale

3 regulatory approved manufacturing facilities with 731 KL capacity

US FDA approved R&D center with best in class infrastructure



## **Capability**

Portfolio of 75+ products across 10 therapeutic categories

846+ filings with regulators

1000+ employees including ~200 scientists



### Reach

80+ countries of presence

75% of revenues through exports

93% of revenues through regulated markets

## **Our Journey**



#### 1984-2003

- Incorporation in 1984 and IPO in 1994
- Sale of first API in 1986
- First USFDA audit in 1997- one of the few Indian companies of our size to get audited by FDA
- Long term customer relationships

#### 2004-2012

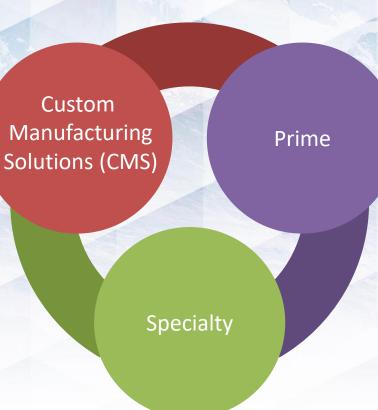
- Investments in capacity expansion
- Initiation of R&D activity at group level
- Foray into Japan and US by way of local presence through subsidiaries
- Entry into peptides business

## **2013-Today**

- Strategic alignment of business towards niche APIs and Custom manufacturing solutions
- Cleared 13<sup>th</sup> USFDA audit without failure
- Focus on profitable growth with 100% API commitment and robust compliance framework

## **Business Verticals**

Work executed exclusively for the customers on products at various phases of their life-cycle<sup>(2)</sup>



Mature APIs, typically with high competition in the API space

Prime APIs and Specialty
APIs collectively form
Generic Drugs Substance
(GDS) for Neuland

APIs with complex processes and niche presence

# **Generic Drug Substance(GDS)**

### **Capability**

- 3 US FDA and EU GMP compliant manufacturing facilities
- Collective capacity: ~731KL

### **Capability**

- High end complex chemistry capabilities
- Backend support by research and development department
- Experience of hurdle free scale up

#### **Prime APIs**

#### **Business Approach**

- Work on molecules either with a business leadership approach or partnership with client on COGS
- Ensure uninterrupted supply with quality commitment

## **Speciality APIs**

#### **Business Approach**

 Work with leading companies and help them to meet their technical requirements while being competitive

#### **Strategy Forward**

- Maintain leadership position in key molecule
- Work on process optimization to improve yields, productivity and thus margins

#### **Strategy Forward**

- Focus on niche APIs with complex chemistry
- File 2-4 products each year for commercial scale up
- File IP for non infringing processes

Robust manufacturing base placed on the foundation of quality and pureplay API commitment

# **Custom Manufacturing Solutions(CMS)**

#### **Services**

- Manufacturing API to customer specifications
- Designing and developing manufacturing processes
- Process optimization for competitiveness
- Filing of DMF/CMC for the API
- Patent protection for processes

### **Business Approach**

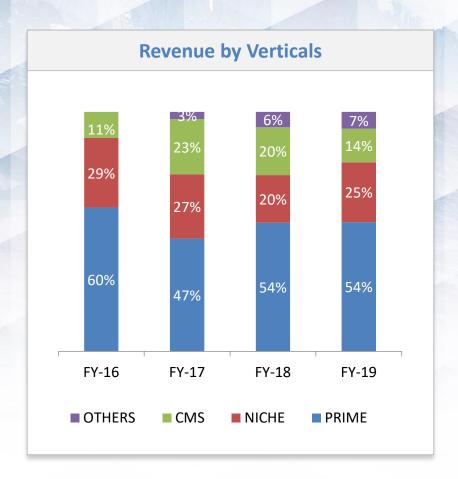
- Local presence in US and Japan with technical as well as commercial employees
- Consultative approach on customer relationships
- Business targeted on Neuland's technology capabilities and perceived customer needs leading to increased traction

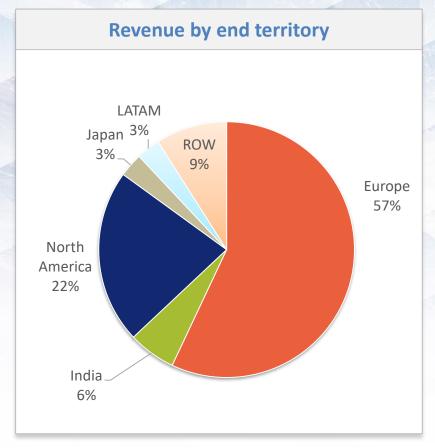
### **Strategy Forward**

- Add depth in technical capabilities
- Investment in QBD labs, process engineering and foray into new areas of customer solutions
- Work effectively on customer relationships and leverage on portfolio expansion
- Targeting molecules in the later stages of the clinical cycle

Create a sustainable CMS business that is driven by technology and strong customer relationships

# **Business Mix**







# **Capabilities**

# **Neuland Manufacturing Facilities**

Unit	U1, Bonthapally, Hyderabad 222.5 KL	U2, Pashamylaram, Hyderabad 310.2 KL	U3, Gaddapotharam, Hyderabad 197 KL	
Year of establishment	1986	1994	2017*	
Employee strength	399	321	140	
Key products	Mirtazapine, Sotalol Hcl, Levetiracetam, Levofloxacin, Salmeterol, Salbutamol, NCE APIs, Peptide APIs, Vitamin D2 analogues	Ciprofloxacin Hcl, Entacapone, NCE APIs, Intermediates & RSMs	Products including Key Intermediates	
Regulatory	USFDA, EDQM, CFDA, PMDA, et. al	USFDA, EDQM, PMDA, ANVISA, et. al	Inspected by USFDA in 2015	

Adding capacities for backward integration and new business

## One state of art R&D centre

### **R&D Facility, Hyderabad**



Location	Bonthapally
Area	■ 3382.5 sq mts
Year of Establishment	<b>2</b> 008
Expertise	<ul> <li>~200 experienced, qualified scientists (&gt;30 PhDs and multiple Post- graduates)</li> </ul>
	4 PhDs and 11 M.Scs for the Peptides Lab

#### Infrastructure

- 11 Development Labs
- 60 Fume hoods
- Analytical Lab
- Kilo Lab dedicated for Scale up
- Dedicated Labs for Peptides
- Separate facility for D2 analogues

#### **Significant R&D Achievements:**

- Several NCE APIs added in NDA or commercial stage drugs
- Support for multiple APIs each year in Phase 2 and Phase 3 clinical candidates
- Generic API business:
  - 600+ DMFs filed
  - 300+ API processes developed
  - 50+ patents filed. Recently received USPTO patent for improved process synthesis of Paliperidone Palmitate

Leveraging on Manufacturing and R&D base to create a synergistic business

# **Compliance Framework**

### **Quality Control**

- Quality Control facilitated with Wet Chemistry, Instrumentation & Microbiology Laboratories
- Equipped with sophisticated instruments like HPLCs, GCs, FTIR, UV & Particle Size Analyzer
- About 50+ chemists perform activities around the clock in 3 shift operations
- Stability studies as per ICH guidelines

#### **EHS**

- Hazard and EHS Impact studies regularly conducted
- 24X7 occupational health center with ambulance facility
- Effluent treatment plant with RO system and solids waste







# **Regulatory Filings**



54

DMFs with USFDA



Health Canada

30

Filings with Health Canada



18

filings with KFDA Korea



Japanese DMF filed



18

filings with TGA



18

China DMF filed



~453

EUDMF filings across Germany, France, Poland, Italy etc





21

CEPs Received for different products

846+

Filings till date



# **Financials**

## **Standalone Financial Performance**

#### Standalone Q2FY20 (Y/Y)

- Total Revenue was Rs. 1,867.9 mn as compared to Rs. 1,693.8 mn, reflecting an increase of 10.3%
- EBITDA stood at Rs. 254.0 mn as compared to Rs. 152.9 mn
- EBITDA Margin at 13.6% for Q2FY 20 as against 9.03%
- Net profit stood at Rs. 85.7 mn for Q2FY20 as compared to Rs. 44.0 mn
- Basic EPS stood at Rs. 6.68 as against Rs. 3.43

### Standalone Q2FY20 (Q/Q)

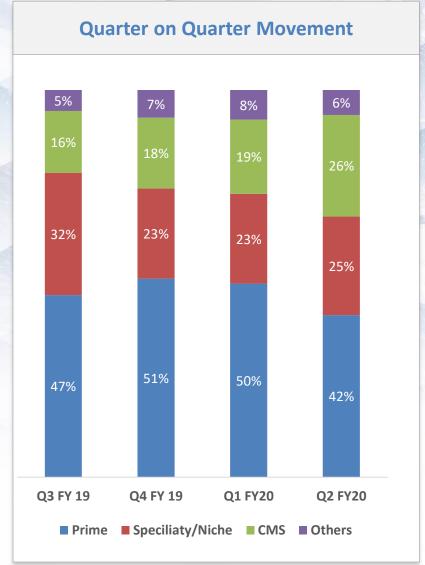
- Total Revenue was Rs.
   1,867.9 mn as compared to
   Rs. 1,815.3 mn, reflecting an increase of 2.9%
- EBITDA stood at Rs. 254.0 mn as compared to Rs. 190.9 mn
- EBITDA Margin at 13.6% for Q2FY 20 as against 10.5%
- Net profit stood at Rs. 85.7 mn for Q2FY20 as compared to Rs. 56.1 mn
- Basic EPS stood at Rs. 6.68 as against Rs. 4.38

### Standalone H1 FY20 (Y/Y)

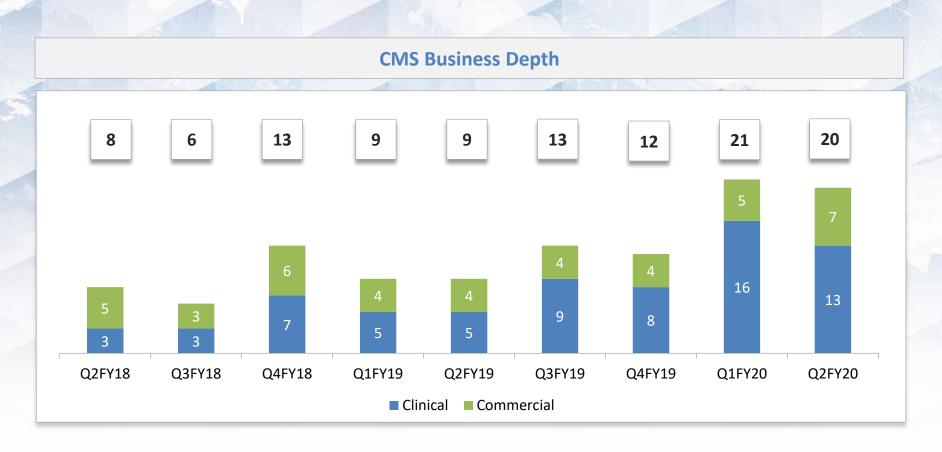
- Total income was Rs. 3,683.1 mn as compared to Rs. 3,244.5 mn, an increase of 13.5%
- EBITDA stood at Rs. 444.9 mn as compared to Rs.253.8 mn, up by 75.3%
- EBITDA Margin at 12.1% for H1FY20 as against 7.8%
- Net profit stood at Rs. 141.9 mn for H1FY20 as compared to Rs. 48.1 mn, an increase of 194.7%
- Basic EPS stood at Rs. 11.06 as against Rs. 3.90, an increase of 183.5%

# **Key Operating Metric**





# **Key Operating Metric**

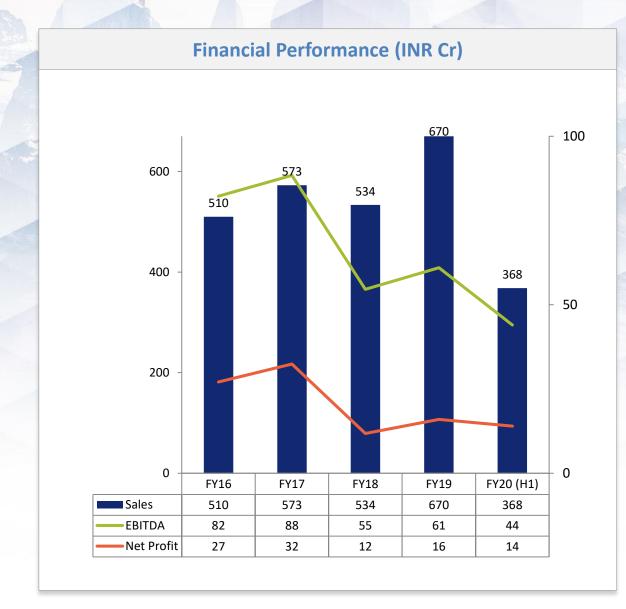


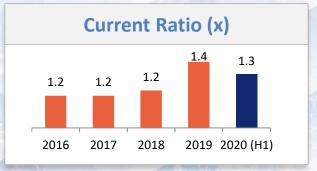
<sup>\*-</sup> Quantities taken for validation and launch are considered as Commercial

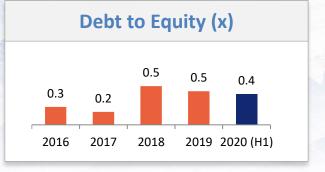
# No of CMS active projects increasing

Q2 FY20	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	<b>Grand Total</b>
API	11	4	6	6	4	6	37
Intermediate	1	3	1	5	11	10	31
<b>Grand Total</b>	12	7	7	11	15	16	68
Q1 FY20	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	<b>Grand Total</b>
API	10	4	5	4	5	6	34
Intermediate	1	3	1	5	9	10	29
<b>Grand Total</b>	11	7	6	9	14	16	63
Q4 FY19	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	<b>Grand Total</b>
API	10	4	2	4	5	5	30
Intermediate	0	2	0	6	8	10	26
<b>Grand Total</b>	10	6	2	10	13	15	56

## **Historical Financials**











# **Future Strategy**

# **Growth Strategy for Business**

#### **Business**

Extend capabilities to organically build a sustainable GDS and CMS business





## Relationships

Scale

Leverage on Long – standing relationships with leading generic and innovator companies

Invest into capacity to

accelerate business growth

augment sales and

## Chemistry

Deploy advanced chemistry skills to add differentiated products to its portfolio







## **Financials**

Re-aligning revenue portfolio for a profitable growth

## Quality

Develop techniques like QBD to stay ahead of the curve & set precedents for "no quality compromise"

Create an organization that results in value for all stakeholders



# Thank you for viewing this presentation.

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