

**Neuland Laboratories Limited**  
11th floor (5th level), Phoenix IVY Building,  
Plot No.573A-III, Road No.82, Jubilee Hills,  
Hyderabad-500033, Telangana, India.



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neulandlabs.com

February 10, 2025

To  
**BSE Limited**  
Phiroze Jeejeebhoy Towers,  
25<sup>th</sup> Floor, Dalal Street,  
Mumbai – 400 001

**The National Stock Exchange of India Ltd**  
Exchange Plaza,  
Bandra Kurla Complex  
Bandra (E), Mumbai – 400 001

**Scrip Code: 524558**

**Scrip Code: NEULANDLAB; Series: EQ**

Dear Sir/Madam,

**Sub: Investors/Analysts Presentation**

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we are enclosing the presentation to the Investors/ Analysts on the Financial Results of the Company for the quarter and nine months ended December 31, 2024.

The presentation is also being uploaded on the website of the Company at [www.neulandlabs.com](http://www.neulandlabs.com).

This is for your information and records.

Yours sincerely,  
For **Neuland Laboratories Limited**

**Sarada Bhamidipati**  
**Company Secretary**

*Encl: As above*

# Neuland Laboratories Limited

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Investor Presentation  
Q3FY25 & 9MFY25

# SAFE HARBOUR

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*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 "forward-looking 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.*

# Table of Content





# Q3FY25 & 9MFY25 Highlights



## **SUCHETH DAVULURI**

*"We saw marginal topline growth this quarter as compared to Q3FY24. Nevertheless, these results align with our initial outlook at the start of the year regarding our expectations for FY25. We are steadily advancing our strategic initiatives and remain optimistic about achieving sustainable long-term growth through acquiring new customers, enhancing our expertise, expanding our capacity flexibly, and refining our processes."*

## **SAHARSH DAVULURI**

*"This quarter's revenues were driven by several important molecules in the commercial CMS and GDS segments. We expect the recently commercialized molecules to scale even as we are on track to enhance our manufacturing capacity. There is good traction from our existing customers reverting for multiple projects as well as fresh interest from a range of new customers. We are seeing increased interest in peptides leading to our recent decision to invest in a larger capacity. Overall, we are confident on the business momentum for the medium as well as long term."*



# Business and Financial Highlights



## 9MFY25 Business and Financial Highlights

### CMS

CMS revenues driven by commercial molecules.

Increasing interest from Biotechs leading to increase in early-stage projects

### GDS

Specialty business driven by Paliperidone and Dorzolamide

In Prime segment Ezetimibe, Mirtazapine and Escitalopram were the key molecules

### Safety and Sustainability

S&P ESG rating of 70

Neuland Labs' Manufacturing Unit III, has been awarded the prestigious Sword of Honour by the British Safety Council

### Free Cash Flow (FCF) generation and utilisation

Generated Free Cash Flow of Rs. 70.8 crores during 9MFY25

Capex Investment of Rs. 147 crores in 9MFY25 vs Rs. 68.2 crores in 9MFY24 (Capex incurred in FY23 - Rs. 66.1 crores, FY24 – Rs. 143.7 crores)

### Working Capital

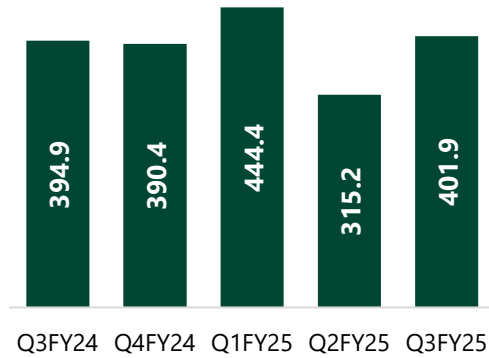
Working capital days of sale at 111 days in Q3FY25 as against 112 days in Q2 FY25, mainly on account of decrease in inventory days.



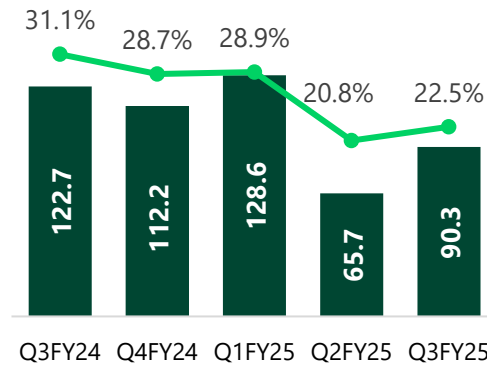
# Q3FY25 Financial Highlights



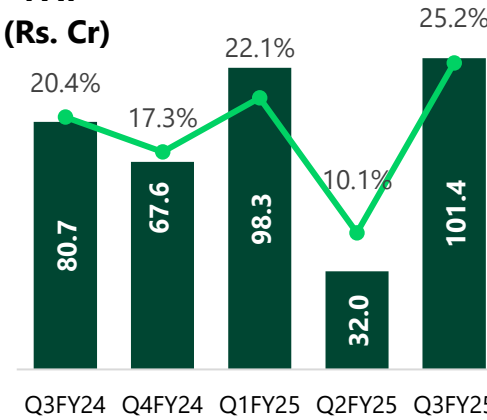
**Total Income  
(Rs. Cr)**



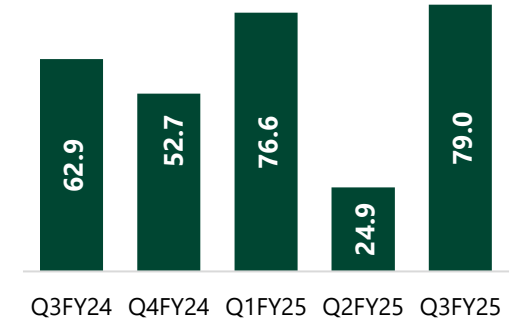
**EBITDA  
(Rs. Cr)**



**PAT\*  
(Rs. Cr)**



**EPS  
(Rs.)**



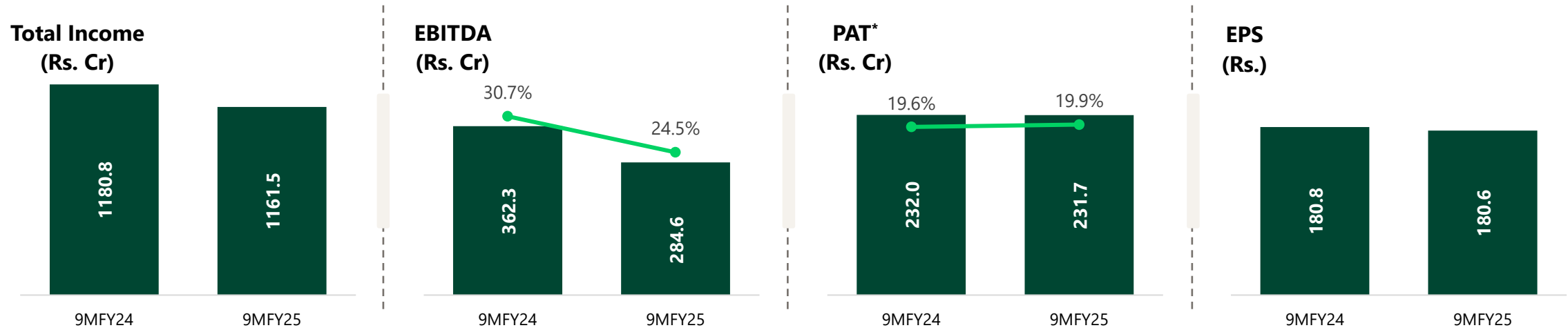
## Financial Highlights

- Total Income for Q3FY25 at Rs. 401.9 crore (+1.8% YoY)
- EBITDA for Q3FY25 at Rs. 90.3 crore (-26.4% YoY)
- EBITDA Margin for Q3FY25 at 22.5% (decreased by 860 bps YoY)
- PAT for Q3FY25 at Rs. 101.4 crore (+25.6% YoY)\*
- Net Debt stood at Rs. (185.1) crore as at Q3FY25 end compared to Rs. (44.6) crore as at Q3FY24 end and Rs (94.3) crore as at Q2FY25 end

\*Q3FY25 and Q1FY25 Includes exceptional item of profit on investment property of Rs. 55.8 crores and Rs. 20.6 crores respectively



# 9MFY25 Financial Highlights



## Financial Highlights

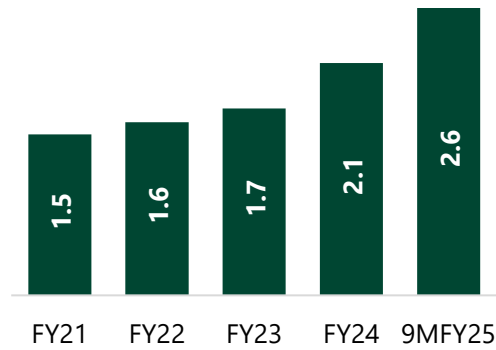
- Total Income for 9MFY25 at Rs. 1,161.5 crore (-1.6% YoY)
- EBITDA for 9MFY25 at Rs. 284.6 crore (-21.5% YoY)
- EBITDA Margin for 9MFY25 at 24.5% (decreased by 620 bps YoY)
- PAT for 9MFY25 at Rs. 231.7 crore (-0.1% YoY)\*
- Net Debt stood at Rs. (185.1) crore as at 9MFY25 end compared to Rs. (44.6) crore as at 9MFY24 end

\*9MFY25 Includes exceptional item of profit on transfer of investment property of Rs. 76.4 crores

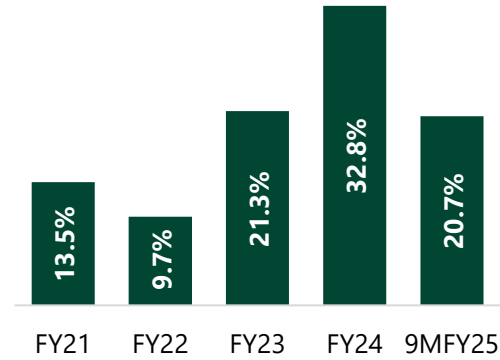
# Key Balance Sheet Metrics



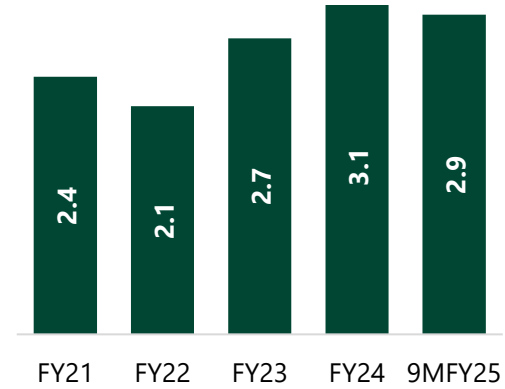
**Current Ratio(x)**



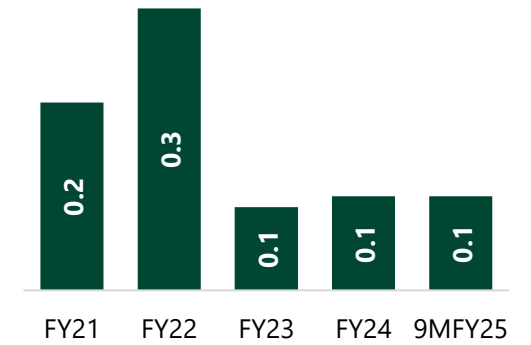
**ROCE (%)**



**Fixed Asset Turnover (x)**



**Debt to Equity (x)**



Particulars (Rs Cr)	Mar-21	Mar-22	Mar-23	Mar-24	Dec-24
Shareholder's Funds	781.9	835.6	988.4	1,276.5	1,489.9
Net Debt*	152.1	212.0	62.9	-32.6	-185.1
Tangible Assets (including CWIP and Investment property)	437.9	497.2	511.2	575.4	672.5
Working Capital	308.6	376.9	463.0	525.4	470.8

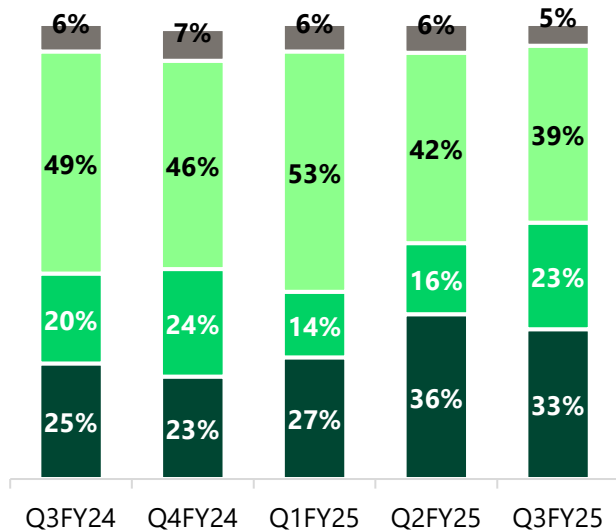
\*Net debt includes investment in Mutual Fund

# Key Operating Metrics Q3FY25



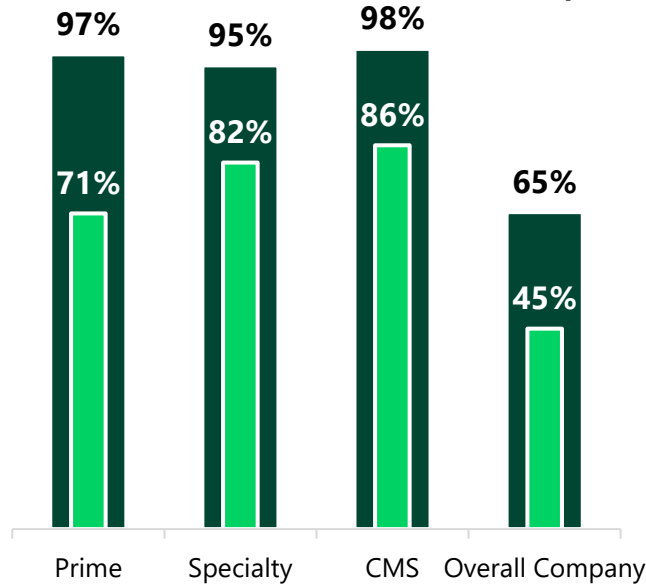
**Segment Revenue**

■ Prime  
■ Specialty  
■ CMS  
■ Others



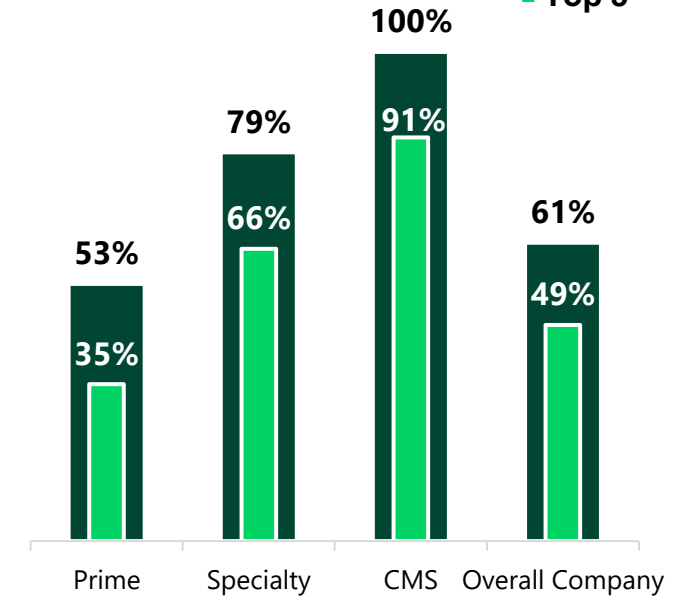
**Top 10 & Top 5 Products**

■ Top 10  
■ Top 5



**Top 10 & Top 5 Customers**

■ Top 10  
■ Top 5



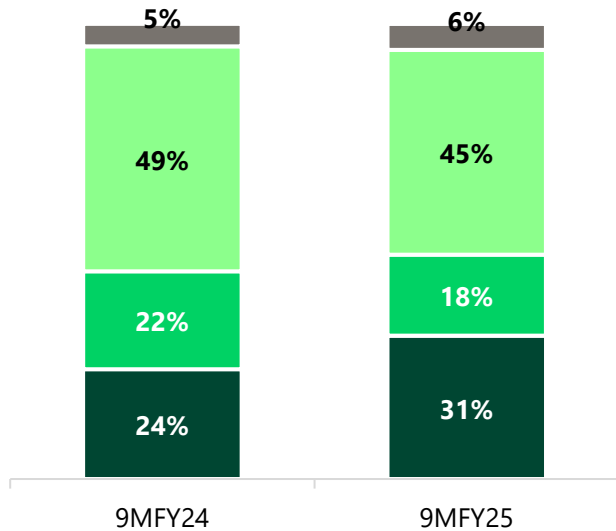
- Steady shift from low margin Prime to high margin Specialty and CMS segments
- CMS business caters to Innovator customers on an exclusive basis, developing and manufacturing APIs/Intermediates in line with rigorous customer expectations hence is highly concentrated in terms of customers
- Specialty segment works on complex products and technologies, hence has a focused approach towards select customers

# Key Operating Metrics 9MFY25



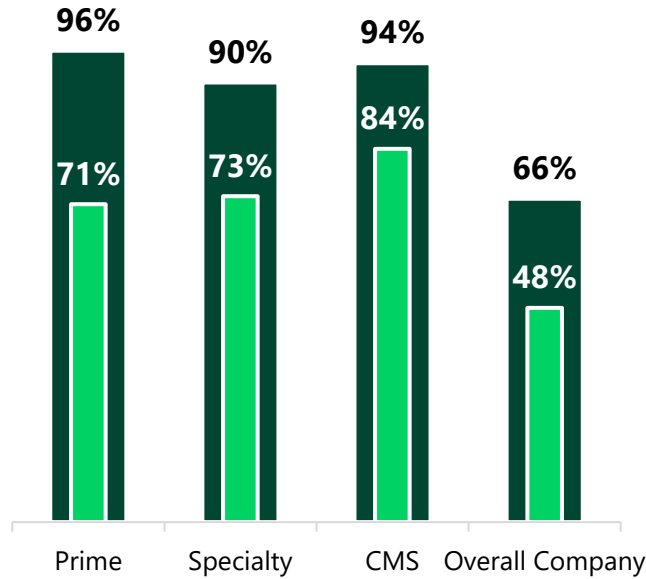
**Segment Revenue**

■ Prime   ■ Specialty  
■ CMS   ■ Others



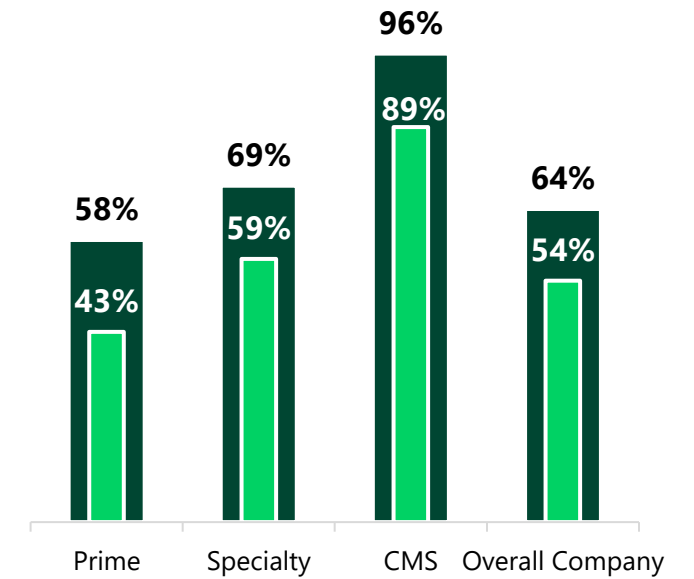
**Top 10 & Top 5 Products**

■ Top 10  
■ Top 5



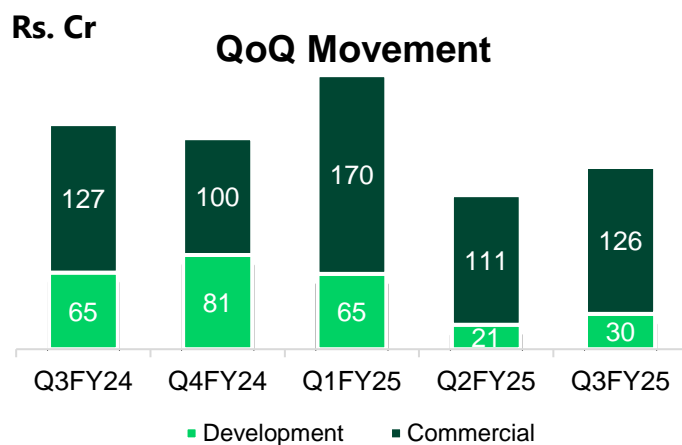
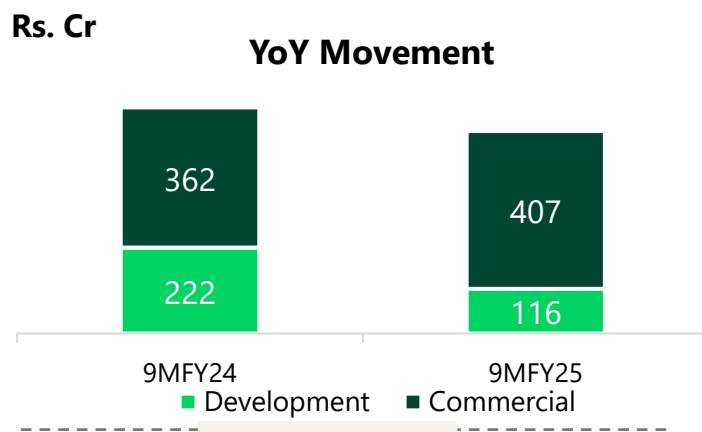
**Top 10 & Top 5 Customers**

■ Top 10  
■ Top 5



- Steady shift from low margin Prime to high margin Specialty and CMS segments
- CMS business caters to Innovator customers on an exclusive basis, developing and manufacturing APIs/Intermediates in line with rigorous customer expectations hence is highly concentrated in terms of customers
- Specialty segment works on complex products and technologies, hence has a focused approach towards select customers

# CMS – Revenue Split & Number of Active Projects



## No. of active CMS projects

Q3 FY25	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	11	10	13	3	6	9	52
Intermediate	9	7	10	4	5	10	45
<b>Grand Total</b>	<b>20</b>	<b>17</b>	<b>23</b>	<b>7</b>	<b>11</b>	<b>19</b>	<b>97</b>

Q3 FY24	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	12	6	12	3	8	8	49
Intermediate	7	4	8	4	6	10	39
<b>Grand Total</b>	<b>19</b>	<b>10</b>	<b>20</b>	<b>7</b>	<b>14</b>	<b>18</b>	<b>88</b>

Q3 FY23	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	17	4	7	5	8	9	50
Intermediate	10	4	4	2	7	12	39
<b>Grand Total</b>	<b>27</b>	<b>8</b>	<b>11</b>	<b>7</b>	<b>15</b>	<b>21</b>	<b>89</b>

Q3 FY22	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	15	3	8	5	10	7	48
Intermediate	7	5	2	0	8	11	33
<b>Grand Total</b>	<b>22</b>	<b>8</b>	<b>10</b>	<b>5</b>	<b>18</b>	<b>18</b>	<b>81</b>

- Pre-clinical to P-3: Neuland generates revenue by process research & development as well manufacturing quantities for clinical trials
- \*Pre-Reg/Reg: Phase-3 complete; Molecules filed but not yet commercial (Earlier labelled as 'Development') or where customer working towards adding Neuland as a second source for a commercial molecule
- Commercial: Neuland generates revenues by manufacturing APIs for commercial novel molecules for innovators
- Steady trend in molecules transitioning from clinical phases to commercialisation resulting in increase in revenue from commercial products



# Company Overview

# Company Overview



Established in

## 1984

40 years in API manufacturing and development



Total reactor volume of

## 941,000 Liters



## ~1700

Employees, 360  
Scientists in R&D



Facilities Inspected by USFDA, EMA, PMDA, Rx-360, TGA, KFDA, ANVISA, WHO



Supported 3 NDA filings and 18 IND filings by supplying APIs and CMC documentation

Commercially Manufactured novel APIs and Intermediates for brands



Expertise in manufacture of Deuterated molecules, Cyanation, Solution and Solid phase peptides.

Cyclic peptides and PEGylated peptides, Hydrogenation, Bromination, Chiral molecules manufacture, Cryogenic reactions, Enzymatic reactions, Synthetic portion of fermented molecules, Micronization (D90 <5 micron)



3 cGMP Manufacturing facilities

Chemical R&D Labs

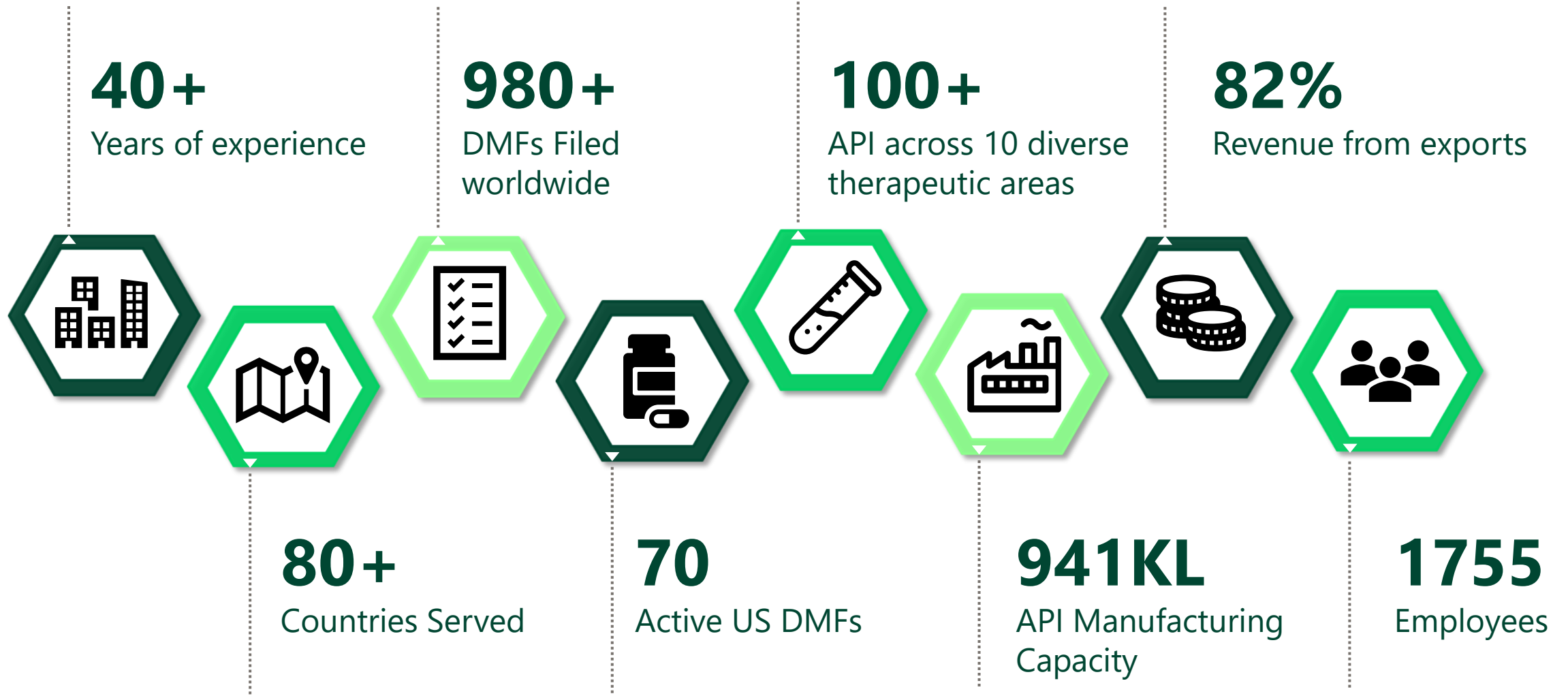
Peptide Labs

Analytical R&D Labs

Process Safety Labs

Hydrogenation Lab

# Key Facts





# Board Of Directors



**Dr. Davuluri  
Rama Mohan Rao**  
Executive Chairman



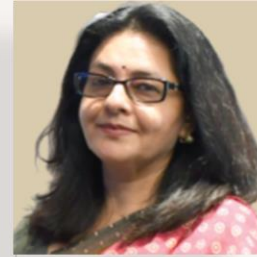
**D. Sucheth Rao**  
Vice Chairman &  
Chief Executive  
Officer



**D. Saharsh Rao**  
Vice Chairman &  
Managing Director



**Dr. Christopher M.  
Cimarusti**  
Non-executive  
Director



**Ms. Pallavi Joshi  
Bhakru**  
Independent  
Director



**Ms. Nirmala Murthy**  
Independent  
Director



**Mr. Homi Rustam  
Khusrokhhan**  
Independent Director



**Mr. Prasad  
Raghavan Menon**  
Independent  
Director



**Mr. Sugata Sircar**  
Independent Director

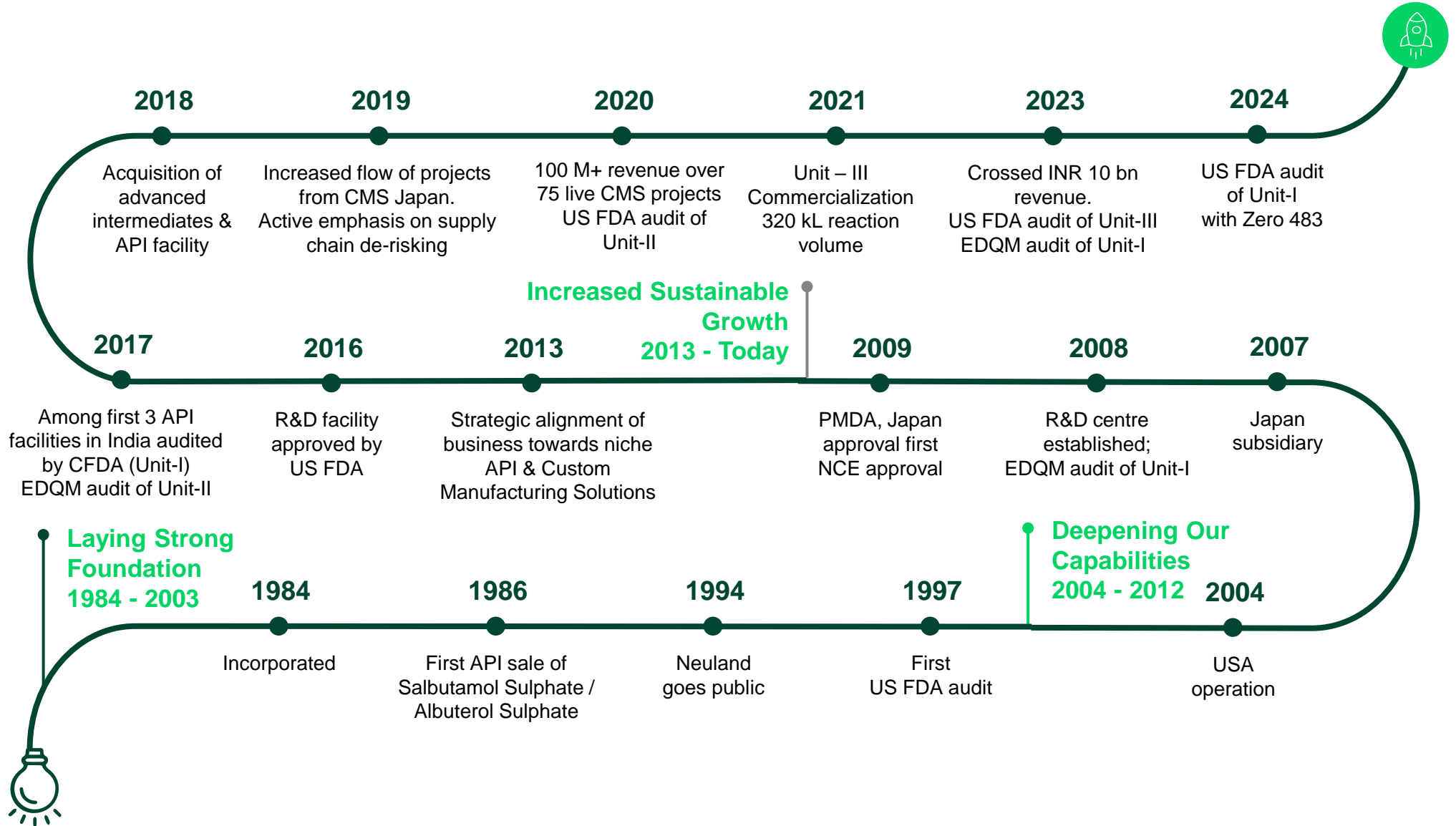
# Key Milestones

## Our Journey

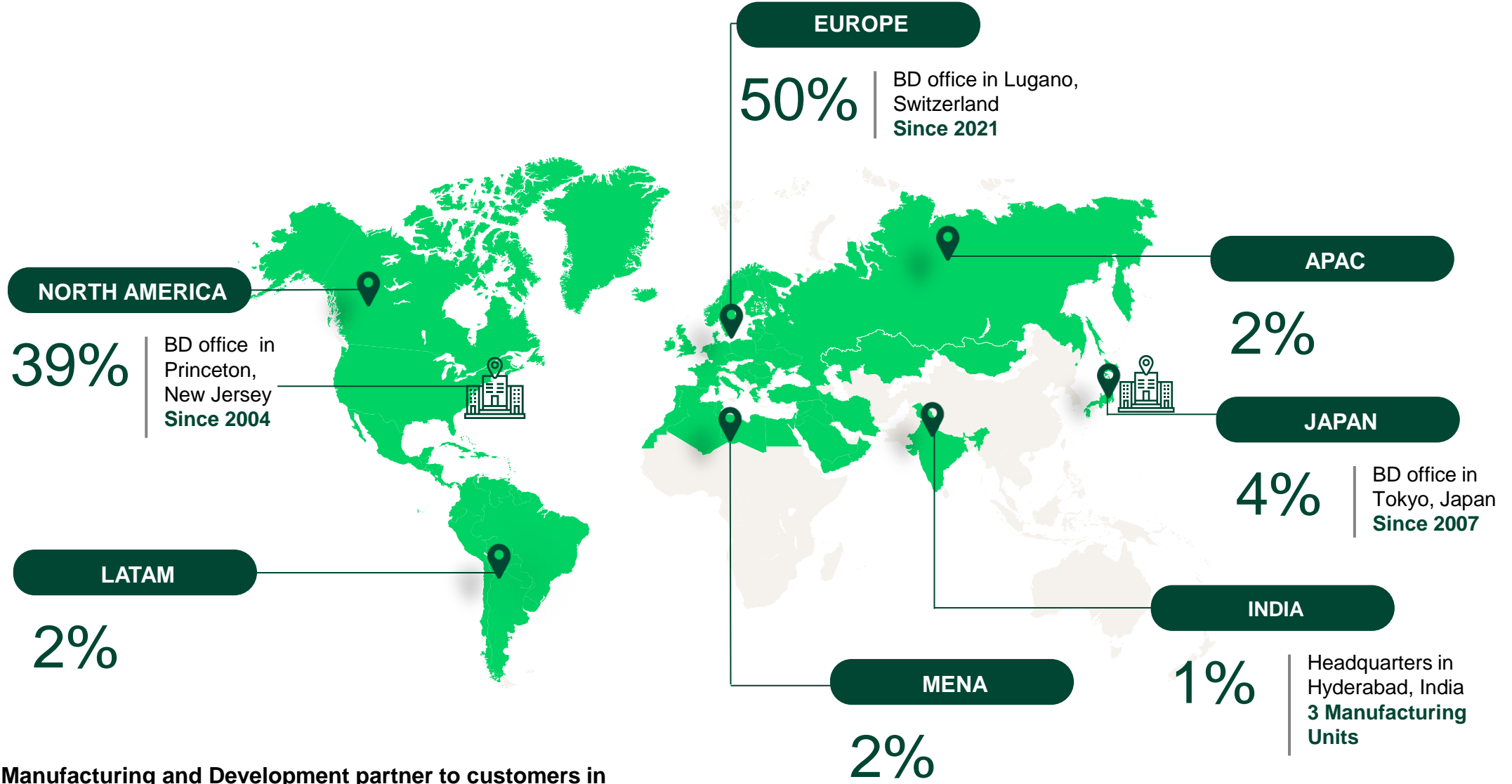


Successfully cleared 17 USFDA inspections

Multiple audits passed with Zero observations



# Our Global Presence\*



Manufacturing and Development partner to customers in over **80 Countries** globally

\* - Based on End-Market revenues – 9M FY25

# Manufacturing Facilities Overview



## UNIT - I

Bonthapally, Hyderabad 239 kL



## UNIT - II

Pashamylaram, Hyderabad 381 kL



## UNIT - III

Gaddapotharam, Hyderabad 321 kL



Year of Establishment

1986

1994

2017



Blocks

Block - 1, 2, 3, 4, H, kL & S

Block-1, 2, 3, FC, NMSM, Mini plant(A&B)

Block - 1, 2, 4, 5, 7 & 8



Hydrogenation Reaction Volume

7.5 kL

6 kL

5 kL



Solvent Recovery System

100 kL/D

20 kL/D

50 kL/D



Cryogenic Reaction Volume

25 kL

17 kL

15 kL



Regulatory

USFDA, EDQM, CFDA, PMDA, Et al.

USFDA, EDQM, PMDA, ANVISA, Et al.

Desktop Inspection by USFDA in 2020;  
USFDA May 2023, ANVISA (Brazil) 2022

**Adding capacities for backward integration and new business**

# State-of-the-art R&D Centre



## Infrastructure

- 15 Development Labs with space for expansion
- 70 Fume hoods
- Analytical Labs
- Dedicated Kilo Lab for Scale up
- Dedicated Labs for Peptides
- Approvals for DSIR, Govt. of India and USFDA
- R&D Team of 360 People
- 600 MHz NMR



Neuland's R&D facility had been inspected by USDFA in February 2016 with zero observations

## 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

- 980+ DMFs filed
- 300+ API processes developed
- 250+ patents filed
- 3 USDMFs filed in FY24
- 2 USDMFs filed till Q3 FY25

# Regulatory Filings



**70**

DMFs with  
USFDA



**32**

Filings with  
Health Canada



**10**

Japanese  
DMF filed



**17**

China DMF  
filed



**20**

Filings with  
KFDA Korea



**28**

Filings with  
TGA



**274**

ROW filings  
including  
Turkey, Mexico,  
Brazil etc.



**~499**

EUDMF filings  
across Germany,  
France, Poland,  
Italy etc.



**30**

CEPs received  
for different  
products



**980+**

Filings till date

**\*\* The numbers on this slide reflect the number of filings, the number of active filings could vary as geographic filings are merged and changes in product portfolio**

# Financial Highlights FY2015-2024



Rs. Cr

	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Total Income	469.9	511.6	588.9	533.7	670.3	766.6	953.0	953.2	1,200.9	1,571.1
EBITDA	67.4	81.5	106.9	54.6	61.4	105.3	162.5	144.3	281.1	474.5
<i>EBITDA Margin</i>	<i>14.3%</i>	<i>15.9%</i>	<i>18.1%</i>	<i>10.2%</i>	<i>9.2%</i>	<i>13.7%</i>	<i>17.1%</i>	<i>15.1%</i>	<i>23.4%</i>	<i>30.2%</i>
PAT	15.8	26.4	46.4	11.8	16.1	15.9	80.3	63.5	163.1	299.6
<i>PAT Margin</i>	<i>3.4%</i>	<i>5.2%</i>	<i>7.9%</i>	<i>2.2%</i>	<i>2.4%</i>	<i>2.1%</i>	<i>8.4%</i>	<i>6.7%</i>	<i>13.6%</i>	<i>19.1%</i>
EPS	18.5	29.7	41.6	10.6	12.8	12.4	62.6	49.5	127.1	233.5
Current Ratio (x)	1.1	1.2	1.3	1.2	1.4	1.4	1.5	1.6	1.7	2.1
ROCE (%)	15.7%	18.4%	15.9%	5.0%	4.7%	8.9%	13.5%	9.7%	21.3%	32.8%
Fixed Asset Turnover (x)	3.8	3.7	3.8	3.2	2.9	2.3	2.4	2.1	2.7	3.1
Debt to Equity (x)	1.1	0.9	0.7	0.5	0.3	0.3	0.2	0.3	0.1	0.1

- Revenue was impacted in FY2018 as a result of mismatch in capacity vs orders. EBITDA margins in FY19 & FY20 were impacted as a result of spike in RM prices, which led Neuland to actively work towards Supply chain de-risking before the COVID19 pandemic
- ROCE was impacted by due to acquisition of unit III in FY2018 which was commercialized in FY2021. Unit 3 utilisation levels have recently started ramping up and momentum is expected to continue



# Business Strategy





# Neuland Strategy Framework





# Our Businesses

# Generic APIs (GDS)



- We are a preferred service provider in the manufacturing of Active Pharmaceutical Ingredients (APIs)
- Have developed processes for over 100 APIs with a strong portfolio of complex molecules
- **Process Investigation Department (PID)** majorly helps our customers to meet their price pressures by way of cutting their total cost of ownership in developing an API thereby achieving excellence in Process development
- API manufacturing heritage of over 40 years
- Flexible 100g to hundreds of tons capacity
- Non-competitive advantage (does not compete in finished formulation)
- Worldwide customer base in 80+ countries
- Proven project management systems
- Impeccable EHS record

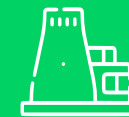


**Facilities &  
Capacity**



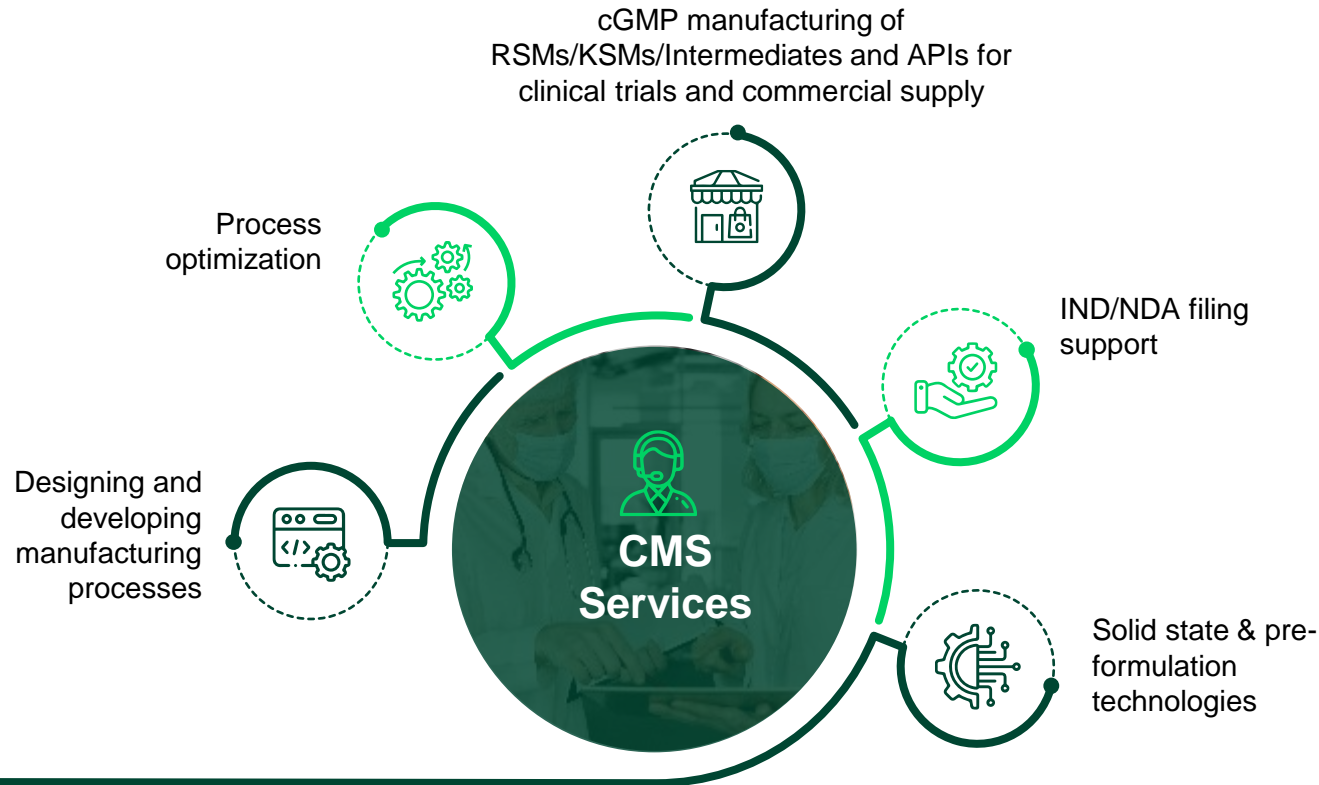
Three US FDA and  
cGMP compliant  
manufacturing facilities

100 APIs across 10  
diverse areas



Total capacity of the reactor volume  
**941,000 liters**

# CDMO Services (CMS)



## Chemistry & manufacturing capabilities

Synthetic portion of fermented molecules

Deuterated molecules

Peptides in solid, solution phase & hybrid technology

Cyanation, hydrogenation, bromination, cryogenic

Steroidal bile acids & vitamin D derivatives

Carbohydrate chemistry

Cyclic and PEGylated peptides

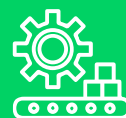
Organometallic carbon-carbon bond formation

Heterocyclic compounds

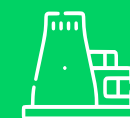
Chiral compounds manufacturing



**Facilities & Capacity**



Three US FDA and cGMP compliant manufacturing facilities

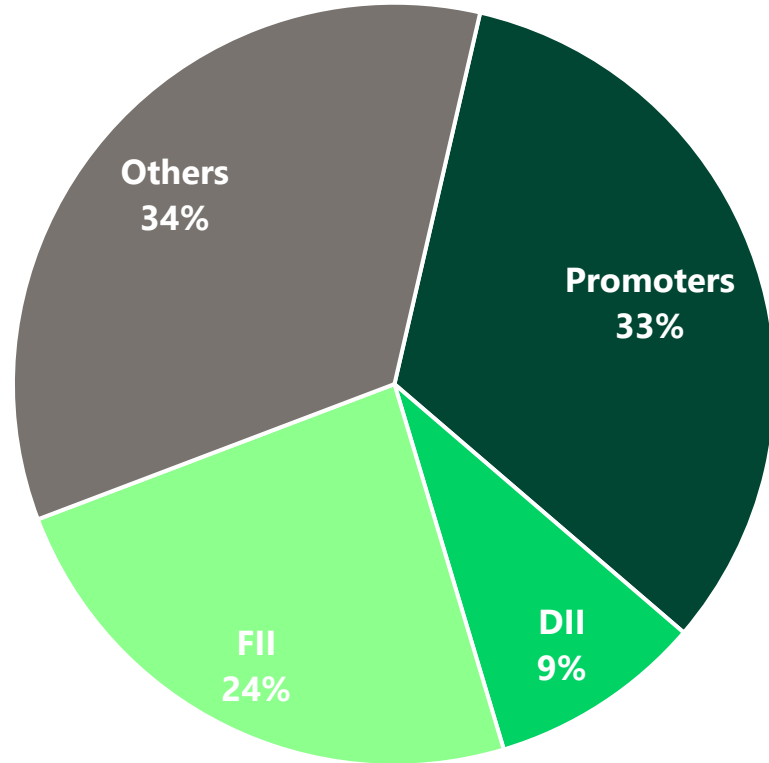


Total capacity of the reactor volume  
**941,000 liters**



# Shareholder Information

# Shareholding Details



## Share Information (as on 31<sup>st</sup> December 2024)

NSE Ticker	NEULANDLAB
BSE Ticker	524558
Market Cap (Rs. Cr)	17,613
% free-float	67.36%
Free-float market cap (Rs. Cr)	11,864
Shares Outstanding	1,28,29,889
3M Average Daily Traded Volume (ADTV) (Shares)*	66,228
3M Average Daily Traded Value (In Rs. Cr)*	99.73
Industry	Pharmaceuticals

\* Source: BSE & NSE



# Annexure

# Profit & Loss Snapshot (Standalone)



Particulars (Rs Cr)	Q3FY25	Q3FY24	YoY (%)	Q2FY25	QoQ (%)	9MFY25	9MFY24	YoY (%)
Total Income	401.9	394.9	1.8%	315.2	27.5%	1,161.5	1,180.8	-1.6%
EBITDA	90.3	122.7	-26.4%	65.7	37.5%	284.6	362.3	-21.5%
EBITDA Margin	22.5%	31.1%	-860 bps	20.8%	170 bps	24.5%	30.7%	-620 bps
Exceptional Item*	55.8	-	-	-	-	76.4	-	-
Profit Before Tax*	127.5	103.8	22.9%	48.5	162.8%	306.4	308.7	-0.7%
PBT Margin	31.7%	26.3%	540 Bps	15.4%	1630 bps	26.4%	26.1%	30 bps
Profit After Tax	101.4	80.7	25.6%	32.0	217.3%	231.7	232.0	-0.1%
PAT Margin	25.2%	20.4%	480 bps	10.1%	1510 bps	19.9%	19.6%	30 bps
EPS (Rs.)	79.0	62.9	25.6%	24.9	217.3%	180.6	180.8	-0.1%

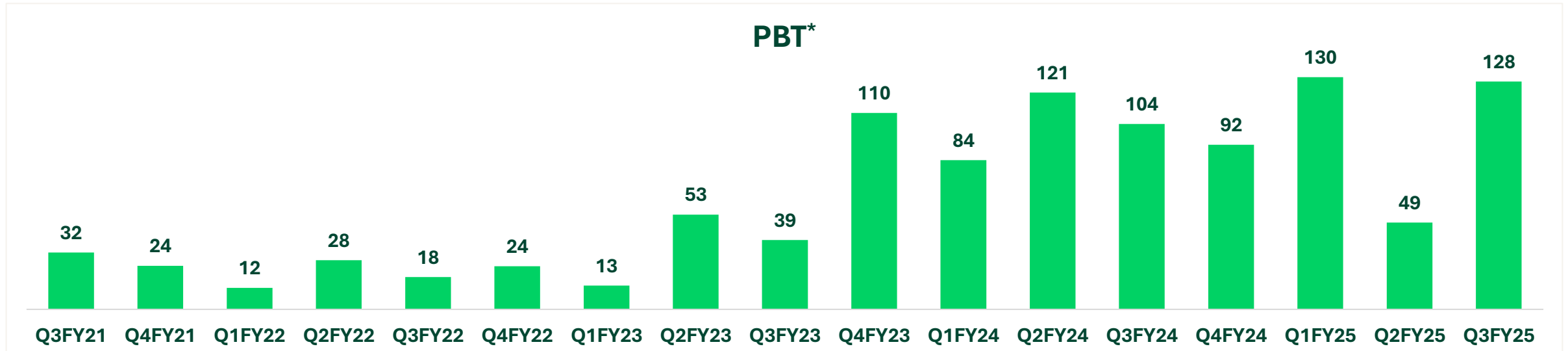
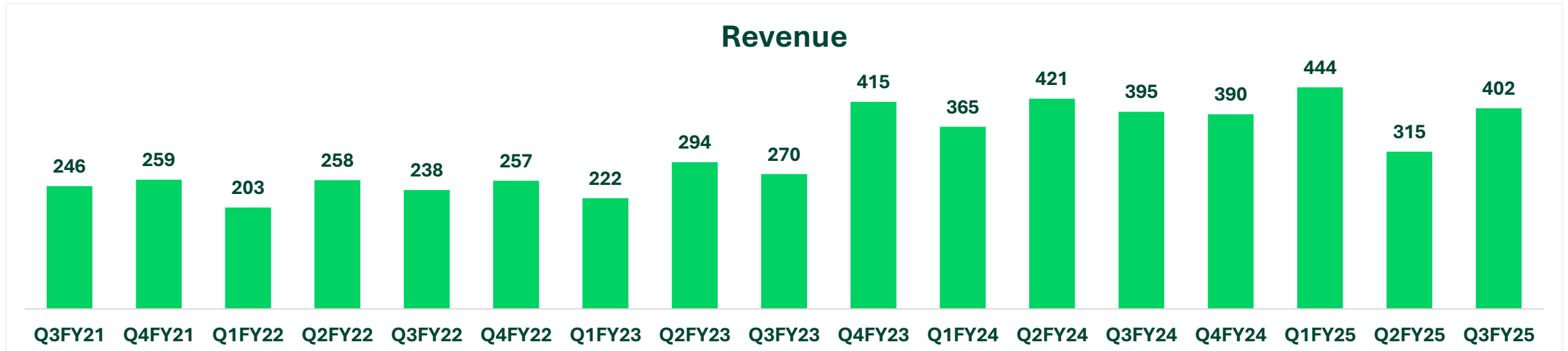
\*Q3FY25 and 9MFY25 includes exceptional item of profit on transfer of investment property of Rs. 55.8 crores and Rs. 76.4 crores respectively



# Revenue & PBT trend



Rs Cr



\*Q3FY25 and Q1FY25 Includes exceptional item of profit on investment property of Rs. 55.8 crores and Rs. 20.6 crores respectively



## Our Vision

We are creating a healthier world through sustainable practices, trusted partnerships, and agile collaboration

## Our Values



### Innovation

Innovative in everything we do



### Transparency

Transparent and open in our communication



### Agility

Agile in our execution



### Accountability

Accountable for our delivery



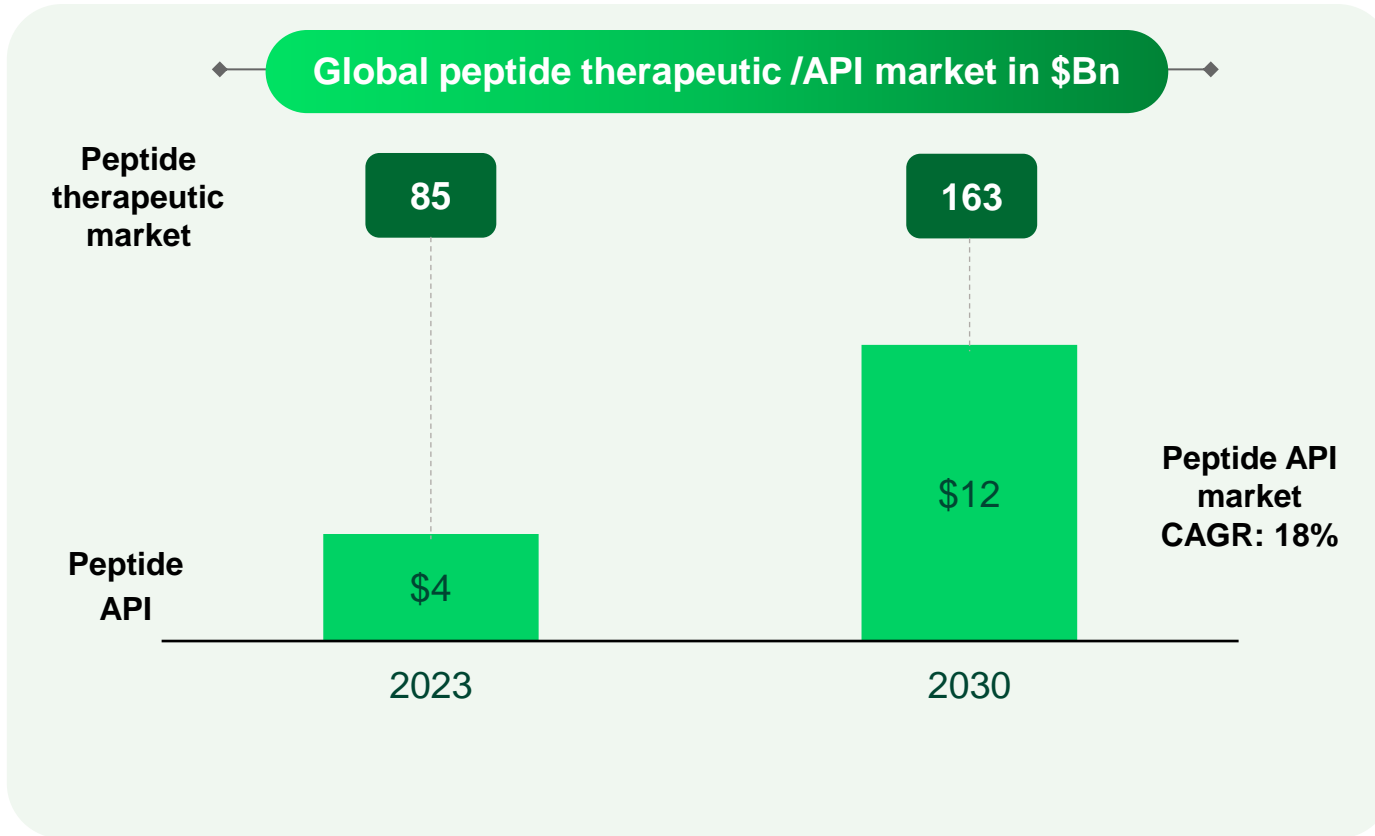
### Empathy

Empathy in all our interactions

## Vision and Values



# Global peptide API market is poised to reach \$14Bn by 2030



## Key market drivers

- **Peptide API market to scale by ~\$14 bn by 2030** driven mainly by rich peptide pipeline and increasing demand for GLP-1.
- **2/3rd of peptides in clinical pipeline are being developed by synthetic routes** while the rest are using the recombinant route.
- **Patent cliff of peptides, broadening the availability of these drugs** as volume increases expected to offset price declines

Neuland has announced a capital expenditure of ₹254 crore to expand its peptide synthesizer reactor capacity from 0.5 KL to 6.37 KL.

# Sustainability Framework



Focus	Our Priorities	Our Commitments	Goal Area	Our Key Goals (included in our Executives' and Leaders' Balanced Scorecard)
 <b>Environment</b>	<ul style="list-style-type: none"> <li>• Effluent and Waste<sup>3,4</sup></li> <li>• Water<sup>3,4</sup></li> <li>• Emissions and Climate Change<sup>3,4</sup></li> <li>• R&amp;D and Innovation<sup>1,4</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Reduction in direct emissions</li> <li>• Efforts to water neutrality</li> <li>• Waste reduction</li> <li>• Reductions in indirect emissions</li> <li>• Sustainable R&amp;D and Innovation</li> </ul>	<b>Direct emissions (Scope 1 and 2)</b>	<ul style="list-style-type: none"> <li>• FY35: Carbon neutrality: 30%* reduction</li> <li>• FY50: Net Zero in absolute emissions (subject to residual – Approx 10%)*</li> </ul>
			<b>Water</b>	<ul style="list-style-type: none"> <li>• FY35: Achieve 25% water neutrality</li> <li>• FY50: Achieve 100% water neutrality</li> </ul>
			<b>Waste</b>	<ul style="list-style-type: none"> <li>• Maintain Zero Waste to Landfill</li> <li>• 100% co-processing of waste</li> <li>• Maintain Zero Liquid Discharge status of effluents</li> </ul>
			<b>Indirect emissions (Scope 3)</b>	<ul style="list-style-type: none"> <li>• FY35: 10%* reduction in indirect carbon emissions (including logistics)</li> </ul>
 <b>Social</b>	<ul style="list-style-type: none"> <li>• Occupational Health and Safety<sup>3,4</sup></li> <li>• Human Capital Development<sup>3,4,5</sup></li> <li>• Community well-being<sup>3,5</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Zero Harm</li> <li>• People well-being and development</li> <li>• Human Rights</li> <li>• Improve Diversity</li> <li>• ESG Awareness and capability building</li> </ul>	<b>Zero Harm</b>	<ul style="list-style-type: none"> <li>• Maintain Zero Fatality</li> <li>• Maintain Nil LTIFR</li> </ul>
			<b>People diversity</b>	FY30: <ul style="list-style-type: none"> <li>• 10% Women in Management Positions</li> <li>• 16% of all hirings will be Women</li> <li>• 0.5% of all employees will be PwD and Other Genders (LGBTQIA+)</li> </ul>
 <b>Governance</b>	<ul style="list-style-type: none"> <li>• Compliance<sup>3,5</sup></li> <li>• Business Continuity and disaster recovery<sup>1,2</sup></li> <li>• Digitalisation<sup>2</sup></li> <li>• Sustainable Supply Chain<sup>2,5</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Ethics and Compliance</li> <li>• Excellence in Corporate Governance</li> <li>• Risk and Crisis Management Capability</li> <li>• Integrity in reporting</li> <li>• Sustainable supply chain</li> </ul>	<b>Sustainable supply chain</b>	FY25: Create a roadmap for sustainable supply chain with key milestones

\*Aligning ESG priorities with our values: [1] Customer Centricity → [2] Reliability → [3] Accountability → [4] Ownership → [5] Openness and transparency

# Glossary



Term	Description
<b>Active Pharmaceutical Ingredient (API)</b>	Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body
<b>Biologic</b>	Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues.
<b>Commercial molecules</b>	Molecules where Neuland is manufacturing for commercial use after the product has been approved
<b>Custom Manufacturing Solutions (CMS)/ Contract Development and Manufacturing Organization (CDMO)</b>	Develop and manufacture pharmaceutical ingredients and intermediates in line with customer expectations.
<b>Development Molecules</b>	Projects where Phase-3 is over, and molecules have been filed but not yet commercial.
<b>DMF</b>	A Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs
<b>GDS</b>	Generic Drug Substance (GDS) segment which includes Prime products and Specialty products
<b>International Council for Harmonisation (ICH) Guidelines</b>	Harmonisation project involving regulatory authorities and pharmaceutical industry to improve efficiency of new drug development and registration processes
<b>New Chemical Entity (NCE)</b>	NCE is granted to “a drug that contains no active moiety that has been approved by FDA in any other application”
<b>Peptides</b>	Peptides are sequences of molecules called amino acids. Peptides of precise sequences may occur naturally in the body, but they may also be produced synthetically or using recombinant DNA technology in bacteria and other living systems. These molecules are used to treat a variety of diseases

Term	Description
<b>Pipeline drugs</b>	Drugs (small or large molecule) under development by a manufacturer
<b>Prime APIs</b>	The prime products which typically include mature APIs with relatively higher competition in API space have historically contributed more than 70% of the total business.
<b>Specialty/ Niche APIs</b>	Molecules in the API space which are complex in nature and are in the nature of ‘high value’ added products and Neuland’s focus has been to develop these molecules from laboratory scale to large commercial quantities
<b>Preclinical study</b>	Preclinical studies take place in animals before any testing in humans is done.
<b>Phase I clinical trial</b>	Researchers test an experimental drug or treatment in a small group of people for the first time.
<b>Phase II clinical trial</b>	The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
<b>Phase III clinical trial</b>	The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
<b>Small molecule products</b>	A drug that can enter cells easily because it has a low molecular weight. Once inside the cells, it can affect other molecules, such as proteins, and may cause cancer cells to die. This is different from drugs that have a large molecular weight, which keeps them from getting inside cells easily. Many targeted therapies are small-molecule drugs
<b>USFDA</b>	The US Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices



# Thank you

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