

**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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neuland@neulandlabs.com  
neulandlabs.com

May 12, 2026

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 year ended March 31, 2026.

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.

Thanking You,

Yours sincerely,  
For **Neuland Laboratories Limited**  
**SARADA**  
**BHAMIDIPATI**  
Digitally signed by  
SARADA BHAMIDIPATI  
Date: 2026.05.12  
16:40:36 +05'30'  
**Sarada Bhamidipati**  
**Company Secretary**

*Encl: As above*

# Neuland Laboratories Limited

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Investor Presentation  
Q4FY26 & FY26

# 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 "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





# Q4FY26 & FY26 Highlights



## **SAHARSH DAVULURI, CEO & MD**

*"We are pleased with the fact that we have ended FY26 on a strong note in line with our original expectations. There is good business visibility in the short to medium term anchored by commercial and near-commercial molecules. Our focus on execution discipline, customer satisfaction, and protection of business fundamentals is central to ensuring this phase of growth.*

*At the same time, we are laying the groundwork for growth beyond this horizon. Key elements of this foundation are the investments in Peptide Manufacturing as well as the new R&D Centre, which are proceeding according to plan. Our Business Development strategy is aligned to the investments and is focused on bringing in the right kind of projects that support high quality, sustainable growth."*



# Q4 & FY26 Business Overview



## **CMS**

CMS revenues driven by commercial molecules.

Growth in new projects orders which will be delivered over the course of this and next financial years.

Traction from Innovators with peptides molecules in pipeline.

## **GDS**

In Prime segment Ezetimibe and Mirtazapine were the key molecules. Ezetimibe likely to drive growth of the Prime segment.

Specialty business subdued due to Paliperidone, revenue driven by Apixaban, Donepezil and Aripiprazole Sterile.

2 New DMF filed for FY26: Vonoprazan and Edoxaban.



## **Financial Highlights**

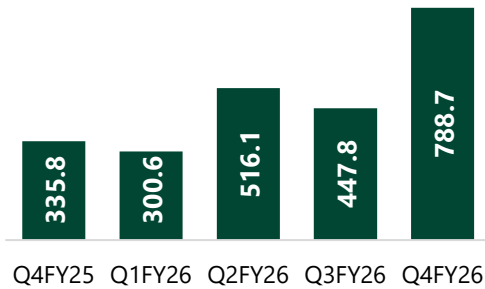
Working capital days of sale at 137 days in Q4FY26 as against 145 days in Q3FY26, mainly on account of decrease in inventory.

Capex outflow of Rs. 397 Cr in FY26.

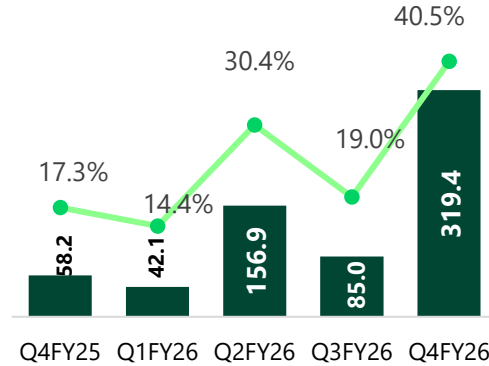
# Q4FY26 Financial Highlights



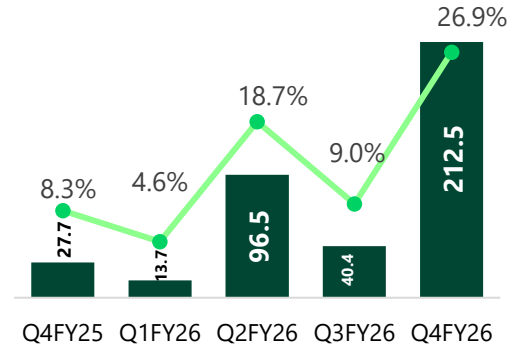
**Total Income**  
(Rs. Cr)



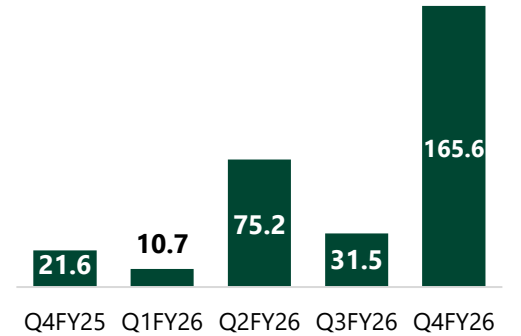
**EBITDA**  
(Rs. Cr)



**PAT**  
(Rs. Cr)



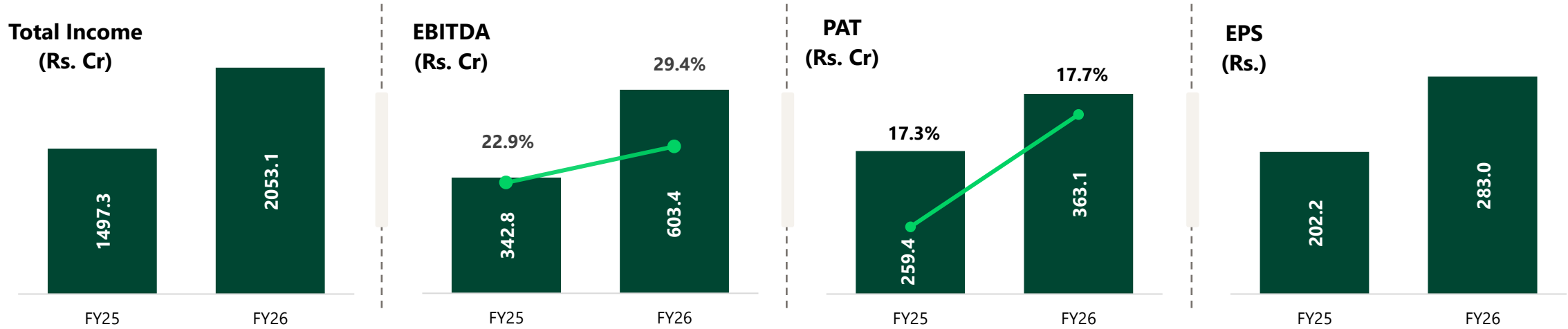
**EPS**  
(Rs.)



## Financial Highlights

- Total Income for Q4FY26 at Rs. 788.7 crore (134.9% YoY)
- EBITDA for Q4FY26 at Rs. 319.4 crore (448.6% YoY)
- EBITDA Margin for Q4FY26 at 40.5% (increased by 2316 bps YoY)
- PAT for Q4FY26 at Rs. 212.5 crore (666.3% YoY)
- Net Debt stood at Rs. (156.8) crore as at Q4FY26 end compared to Rs. (228.7) crore as at Q4FY25 end and Rs (202.6) crore as at Q3FY26 end

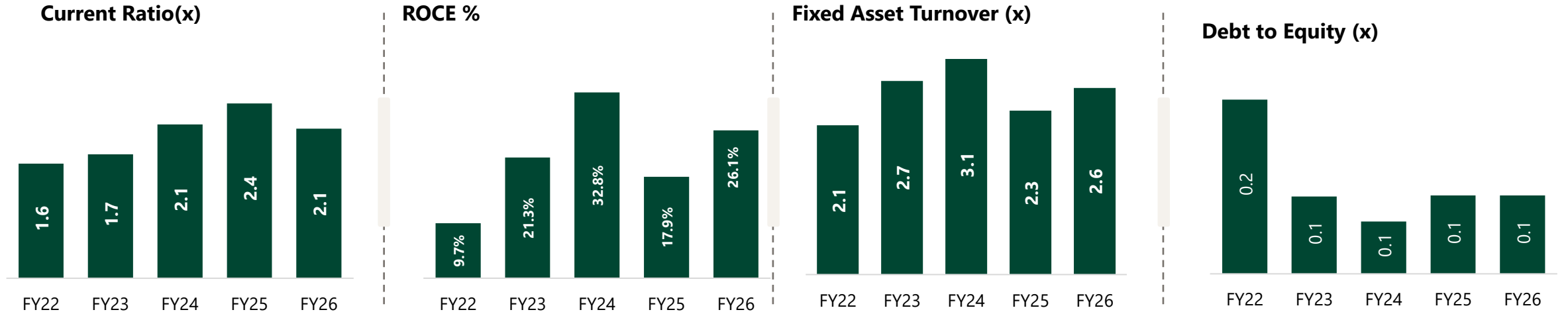
# FY26 Financial Highlights



## Financial Highlights

- Total Income for FY26 at Rs. 2053.1 crore (37.1% YoY)
- EBITDA for FY26 at Rs. 603.4 crore (76% YoY)
- EBITDA Margin for FY26 at 29.4% (increased by 650 bps YoY)
- PAT for FY26 at Rs. 363.1 crore (40% YoY)
- Net Debt stood at Rs. (156.8) crore as at FY26 end compared to Rs. (228.7) crore as at FY25 end

# Key Balance Sheet Metrics



Particulars (Rs Cr)	Mar-22	Mar-23	Mar-24	Mar-25	Mar-26
Shareholder's Funds	835.6	988.4	1,276.5	1,517.8	1,865.9
Net Debt*	212.0	63.0	-32.6	-228.7	-156.8
Tangible Assets (including CWIP)**	497.2	511.2	575.4	698.2	1,002.9
Working Capital	376.9	463.0	525.4	440.6	773.0

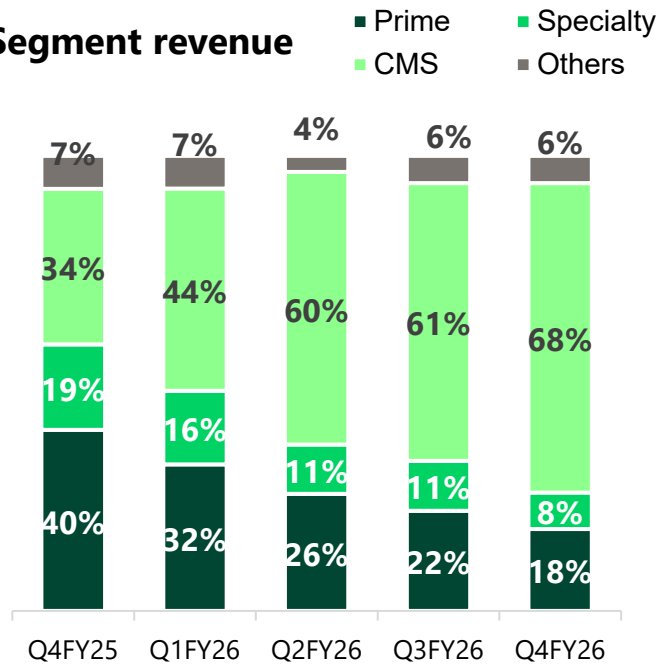
\*Net debt includes investment in Mutual Fund in previous years.

\*\*Tangible assets includes investment property in previous years.

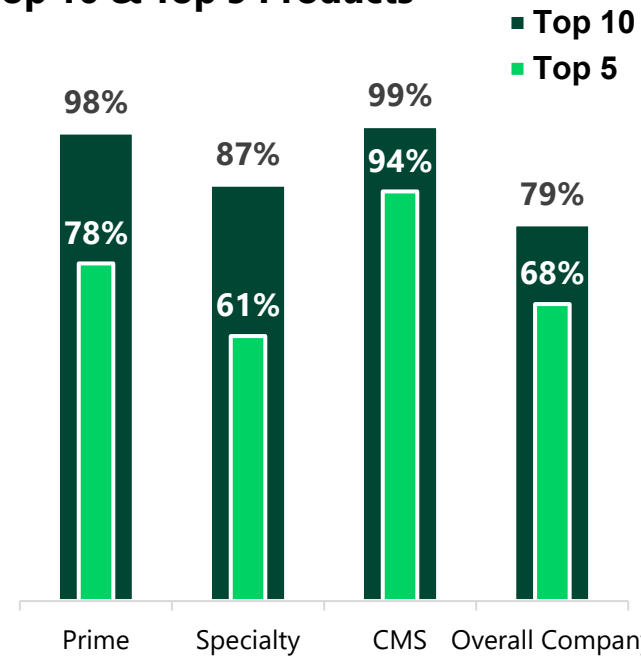
# Key Operating Metrics Q4FY26



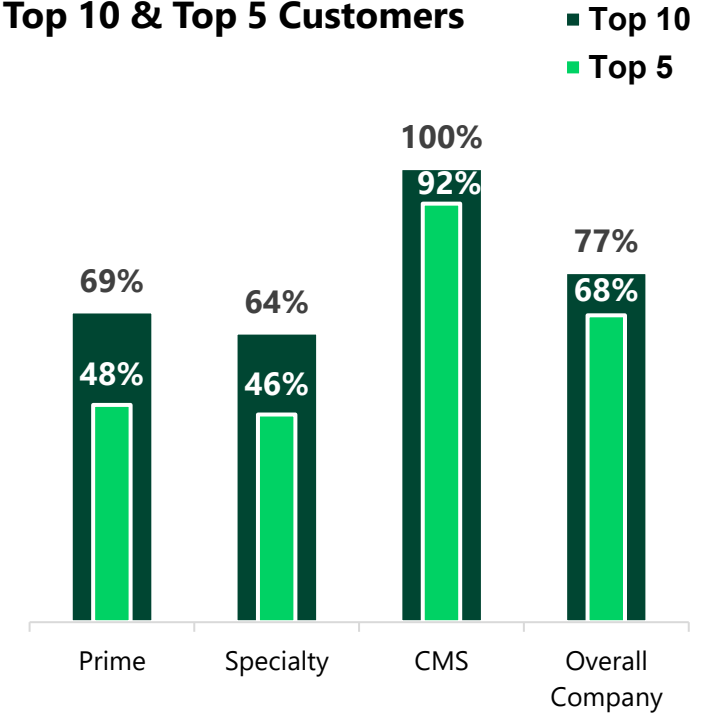
**Segment revenue**



**Top 10 & Top 5 Products**



**Top 10 & Top 5 Customers**



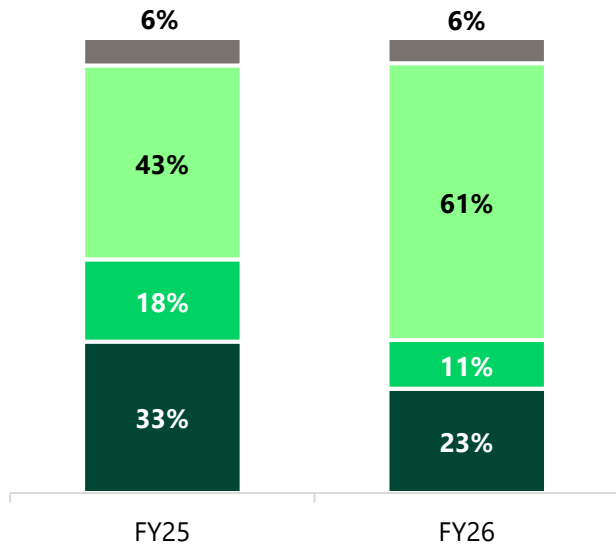
- CMS business caters to Innovator customers on an exclusive basis, developing and manufacturing APIs/Intermediates in line with rigorous customer expectations hence is highly concentrated in terms of customers
- Specialty segment works on complex products and technologies, hence has a focused approach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

# Key Operating Metrics FY26



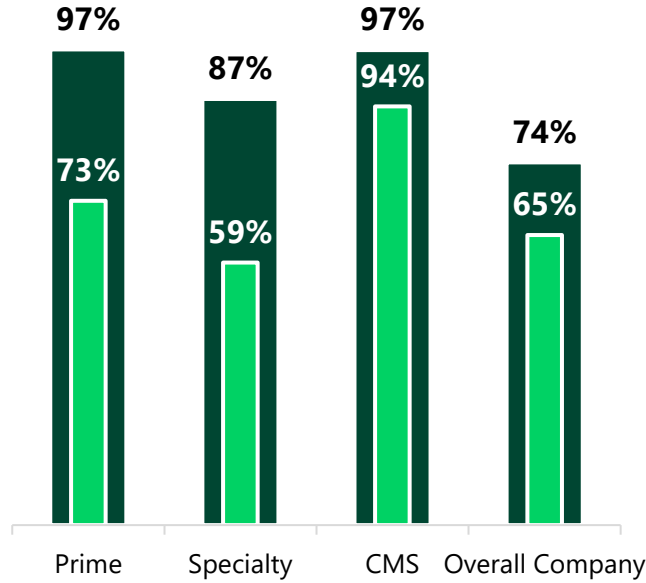
### Segment Revenue

■ Prime    ■ Specialty  
■ CMS    ■ Others



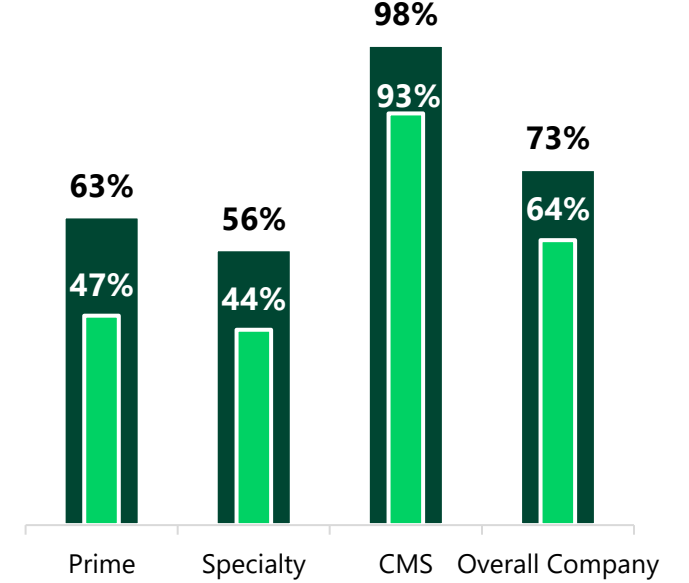
### Top 10 & Top 5 Products

■ Top 10  
■ Top 5



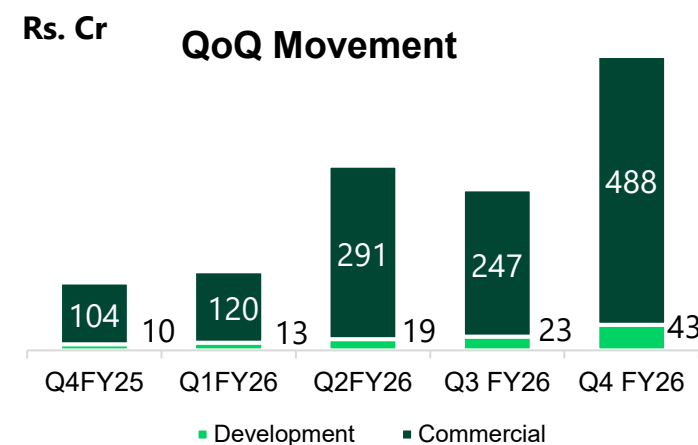
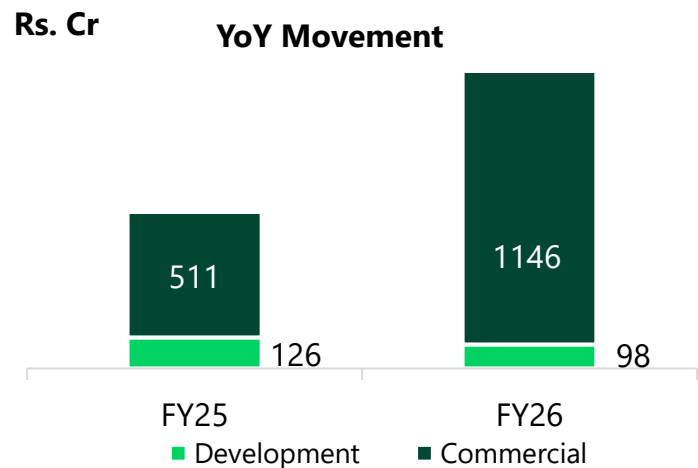
### Top 10 & Top 5 Customers

■ Top 10  
■ Top 5



- 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

Q4 FY26	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	16	13	13	5	3	9	59
Intermediate	4	9	7	5	4	10	39
<b>Grand Total</b>	<b>20</b>	<b>22</b>	<b>20</b>	<b>10</b>	<b>7</b>	<b>19</b>	<b>98</b>

Q4 FY25	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	14	12	13	4	4	9	56
Intermediate	7	8	7	4	5	10	41
<b>Grand Total</b>	<b>21</b>	<b>20</b>	<b>20</b>	<b>8</b>	<b>9</b>	<b>19</b>	<b>97</b>

Q4 FY24	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	8	8	12	3	8	8	47
Intermediate	8	4	9	4	6	10	41
<b>Grand Total</b>	<b>16</b>	<b>12</b>	<b>21</b>	<b>7</b>	<b>14</b>	<b>18</b>	<b>88</b>

Q4 FY23	Pre-Clinical	P-1	P-2	P-3	Pre-Reg/Reg	Commercial	Grand Total
API	15	5	7	4	8	9	48
Intermediate	10	4	4	2	7	12	39
<b>Grand Total</b>	<b>25</b>	<b>9</b>	<b>11</b>	<b>6</b>	<b>15</b>	<b>21</b>	<b>87</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

## 12,26,000 Liters



## ~2188

Employees,  
434 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

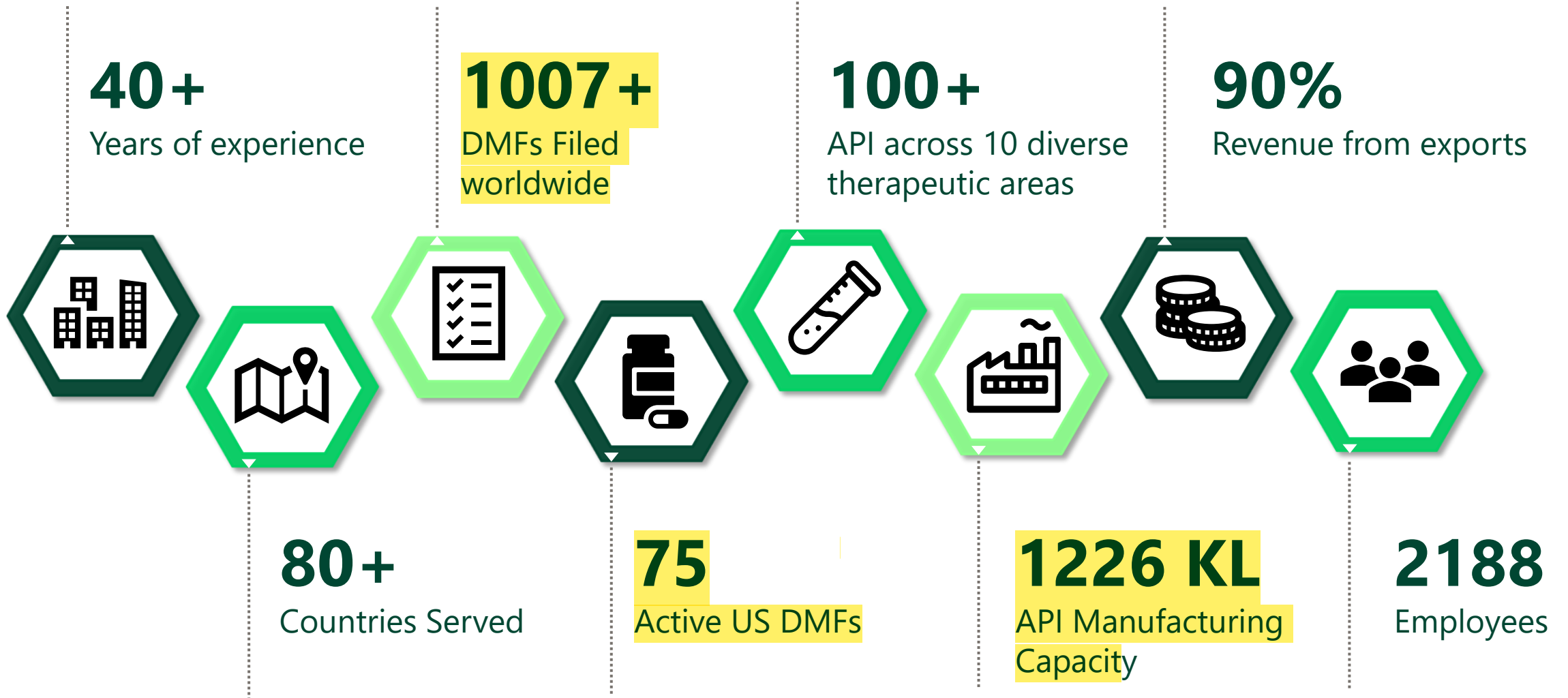
Peptide Labs

Analytical R&D Labs

Process Safety Labs

Hydrogenation Lab

# Key Facts



# Board Of Directors



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



● **D. Sucheth Rao**  
Executive Vice  
Chairman



● **D. Saharsh Rao**  
Chief Executive Officer  
& Managing Director



● **Mr. Prasad  
Raghavan Menon**  
Independent  
Director



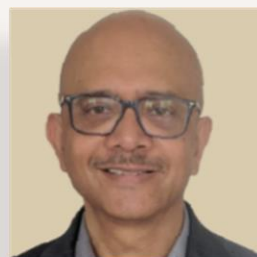
● **Mr. Homi Rustam  
Khusrokhan**  
Independent  
Director



● **Dr. Ravi Shankar  
Gopinath**  
Independent  
Director



● **Ms. Pallavi Joshi  
Bhakru**  
Independent  
Director



● **Mr. Sugata Sircar**  
Independent  
Director



● **Dr. Mauricio  
Futran**  
Additional  
Director

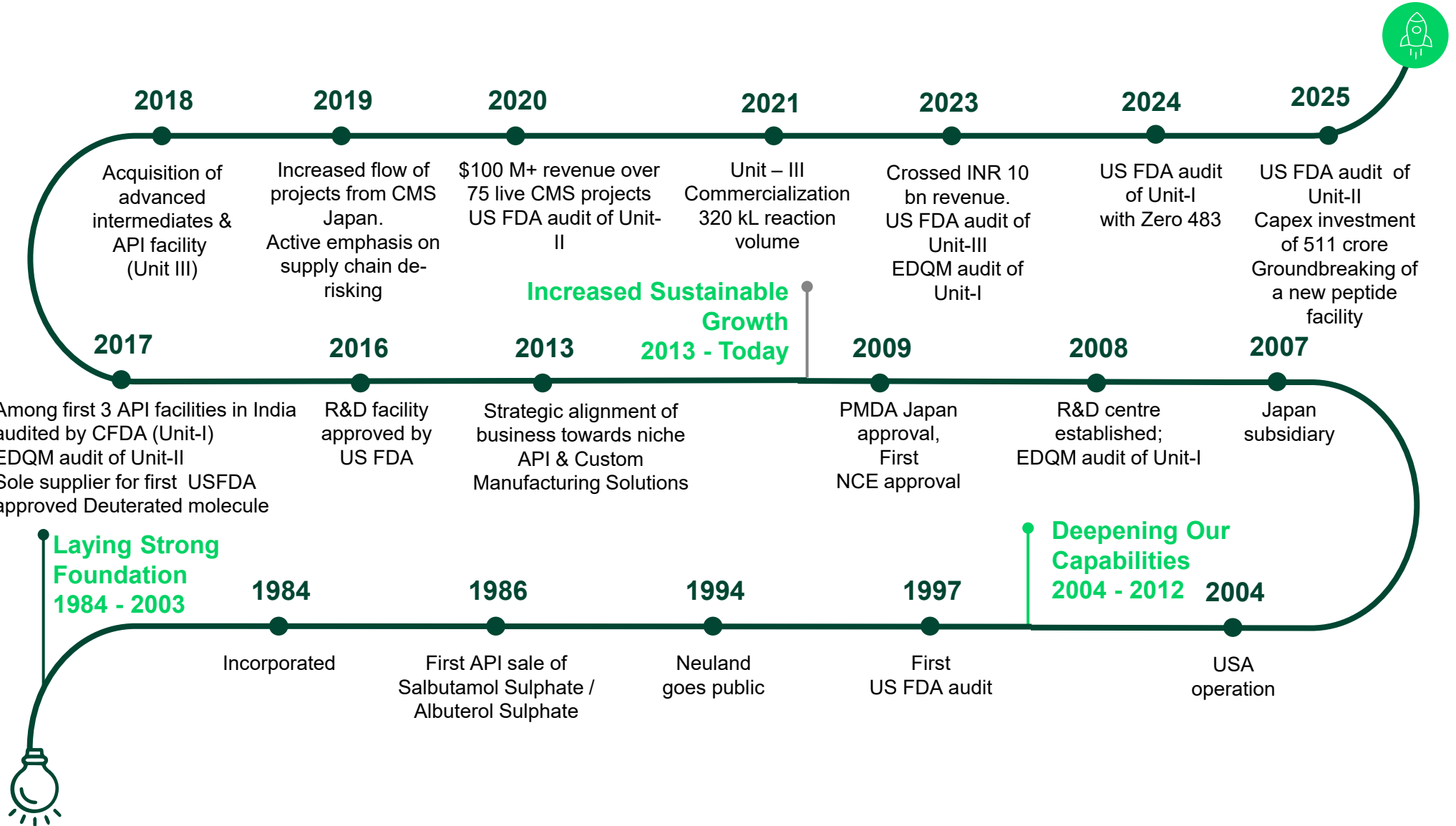
# Key Milestones

## Our Journey

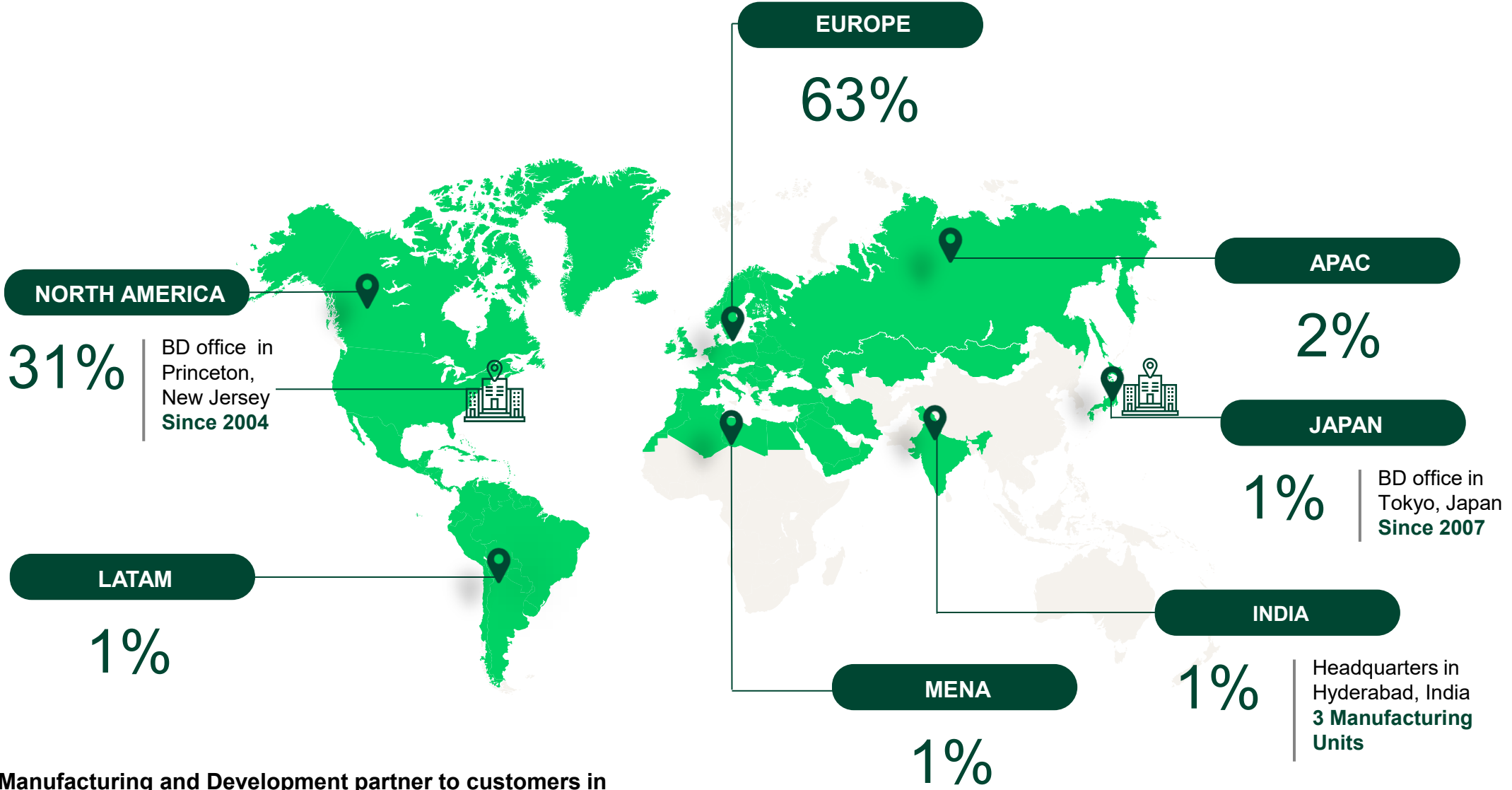


Successfully cleared 18 USFDA inspections

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 – 12M FY26

# Manufacturing Facilities Overview



## UNIT - I

Bonthapally, Hyderabad 256 kL



## UNIT - II

Pashamylaram, Hyderabad 389 kL



## UNIT - III

Gaddapotharam, Hyderabad 581 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, 6, 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 434 People
- 600 MHz NMR

Neuland is set to open its new state-of-the-art research and development center, spanning across 140,000 square feet, in Hyderabad's Genome Valley



Neuland's R&D facility had been inspected by USFDA 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

- 1007+ DMFs filed
- 300+ API processes developed
- 204+ patents filed
- 3 new USDMFs filed in FY26

# Regulatory Filings



**75**

DMFs with  
USFDA



**33**

Filings with  
Health Canada



**10**

Japanese  
DMF filed



**17**

China DMF  
filed



**26**

Filings with  
KFDA Korea



**28**

Filings with  
TGA



**289**

ROW filings  
including  
Turkey, Mexico,  
Brazil etc.



**~499**

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



**30**

CEPs received  
for different  
products



**1007+**

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 FY2017-2026



Rs. Cr

	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026
Total Income	588.9	533.7	670.3	766.6	953.0	953.2	1,200.9	1,571.1	1,497.3	2,053.1
EBITDA	106.9	54.6	61.4	105.3	162.5	144.3	281.1	474.5	342.8	603.4
<i>EBITDA Margin</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>	<i>22.9%</i>	<i>29.4%</i>
PAT	46.4	11.8	16.1	15.9	80.3	63.5	163.1	299.6	259.4	363.1
<i>PAT Margin</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>	<i>17.3%</i>	<i>17.7%</i>
EPS	41.6	10.6	12.8	12.4	62.6	49.5	127.1	233.5	202.2	283
Current Ratio (x)	1.3	1.2	1.4	1.4	1.5	1.6	1.7	2.1	2.4	2.1
ROCE (%)	15.9%	5.0%	4.7%	8.9%	13.5%	9.7%	21.3%	32.8%	17.9%	26.1%
Fixed Asset Turnover (x)	3.8	3.2	2.9	2.3	2.4	2.1	2.7	3.1	2.3	2.6
Debt to Equity (x)	0.7	0.5	0.3	0.3	0.1	0.2	0.1	0.1	0.1	0.1

- FY26 revenues showed a significant increase due to the scale up in key molecules in the CMS business. The increase in revenues impacted other financial metrics as a result of operating leverage.
- 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  
**12,26,000 liters**

# CDMO Services (CMS)



cGMP manufacturing of RSMs/KSMs/Intermediates and APIs for clinical trials and commercial supply



## 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

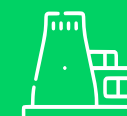
Chiral compounds manufacturing



**Facilities & Capacity**



Three US FDA and cGMP compliant manufacturing facilities

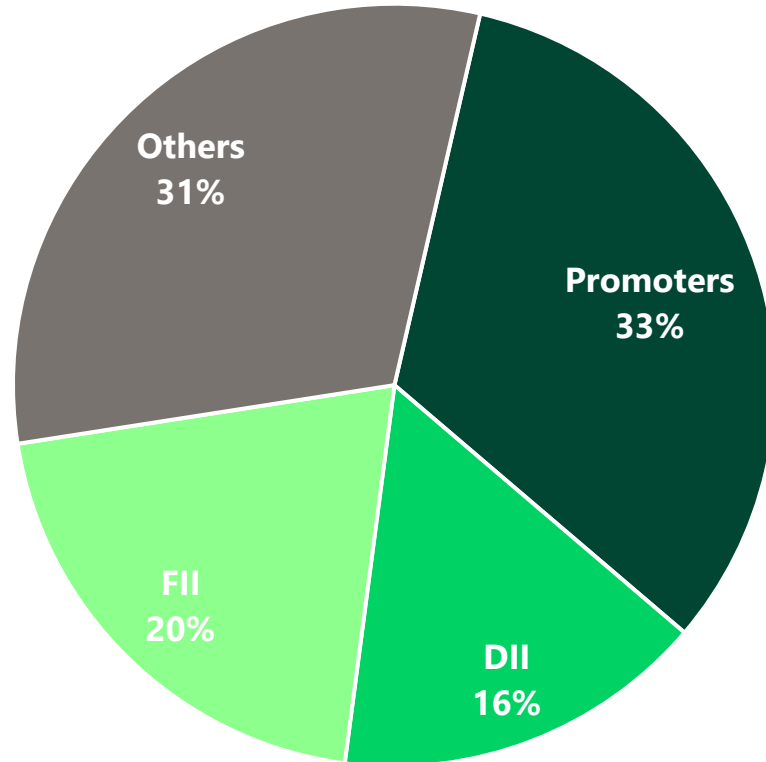


Total capacity of the reactor volume  
**12,26,000 liters**



# Shareholder Information

# Shareholding Details



## Share Information (as on 31<sup>st</sup> Mar 2026)

NSE Ticker	NEULANDLAB
BSE Ticker	524558
Market Cap (Rs. Cr)	15,412.09
% free-float	67.37%
Free-float market cap (Rs. Cr)	10,383
Shares Outstanding	1,28,29,889
3M Average Daily Traded Volume (ADTV) (Shares)*	42,871
3M Average Daily Traded Value (In Rs. Cr)*	57.23
Industry	Pharmaceuticals

\* Source: BSE & NSE



# Annexure

# Profit & Loss Snapshot (Standalone)

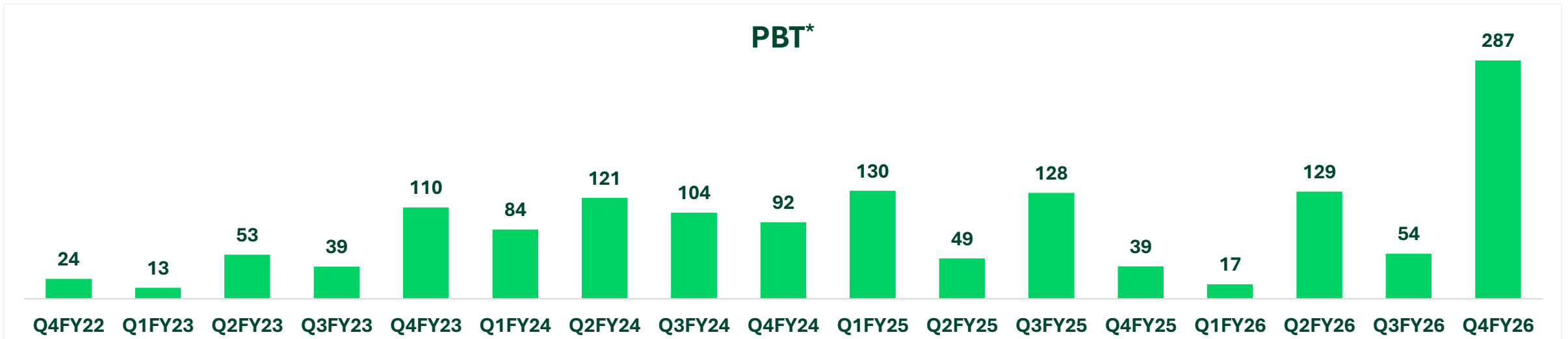
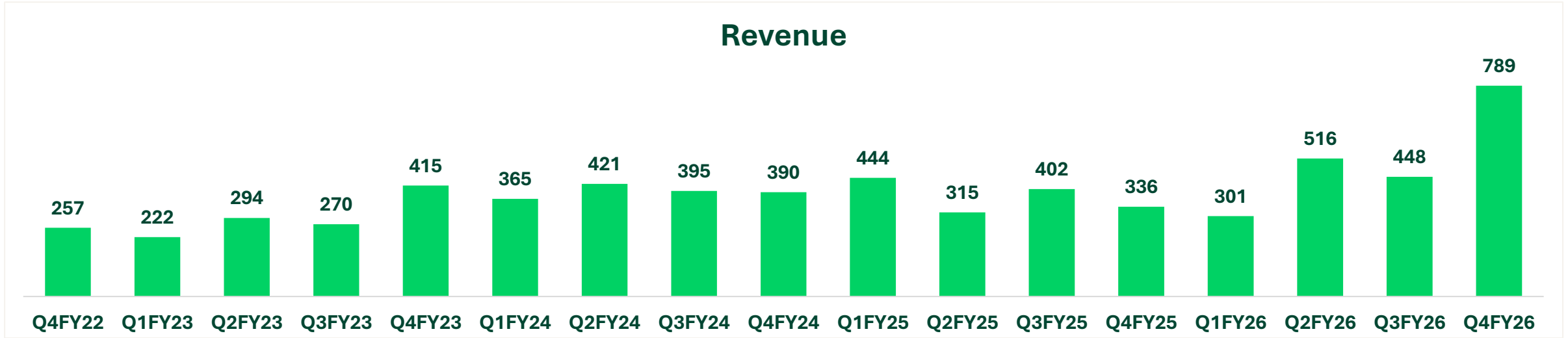


Particulars (Rs Cr)	Q4FY26	Q4FY25	YoY (%)	Q3FY26	QoQ (%)
Total Income	788.7	335.8	134.9%	447.8	76.1%
EBITDA	319.4	58.2	448.6%	85.0	275.8%
EBITDA Margin	40.5%	17.3%	2316 bps	19.0%	2151 bps
Exceptional Item*	-	-	-	-	-
Profit Before Tax*	287.0	39.0	636.6%	54.3	428.9%
PBT Margin	36.4%	11.6%	2479 bps	12.1%	2430 bps
Profit After Tax	212.5	27.7	666.3%	40.4	425.8%
PAT Margin	26.9%	8.3%	1869 bps	9.0%	1789 bps
EPS (Rs.)	165.6	21.6	666.3%	31.5	425.8%

# Revenue & PBT trend



Rs Cr



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



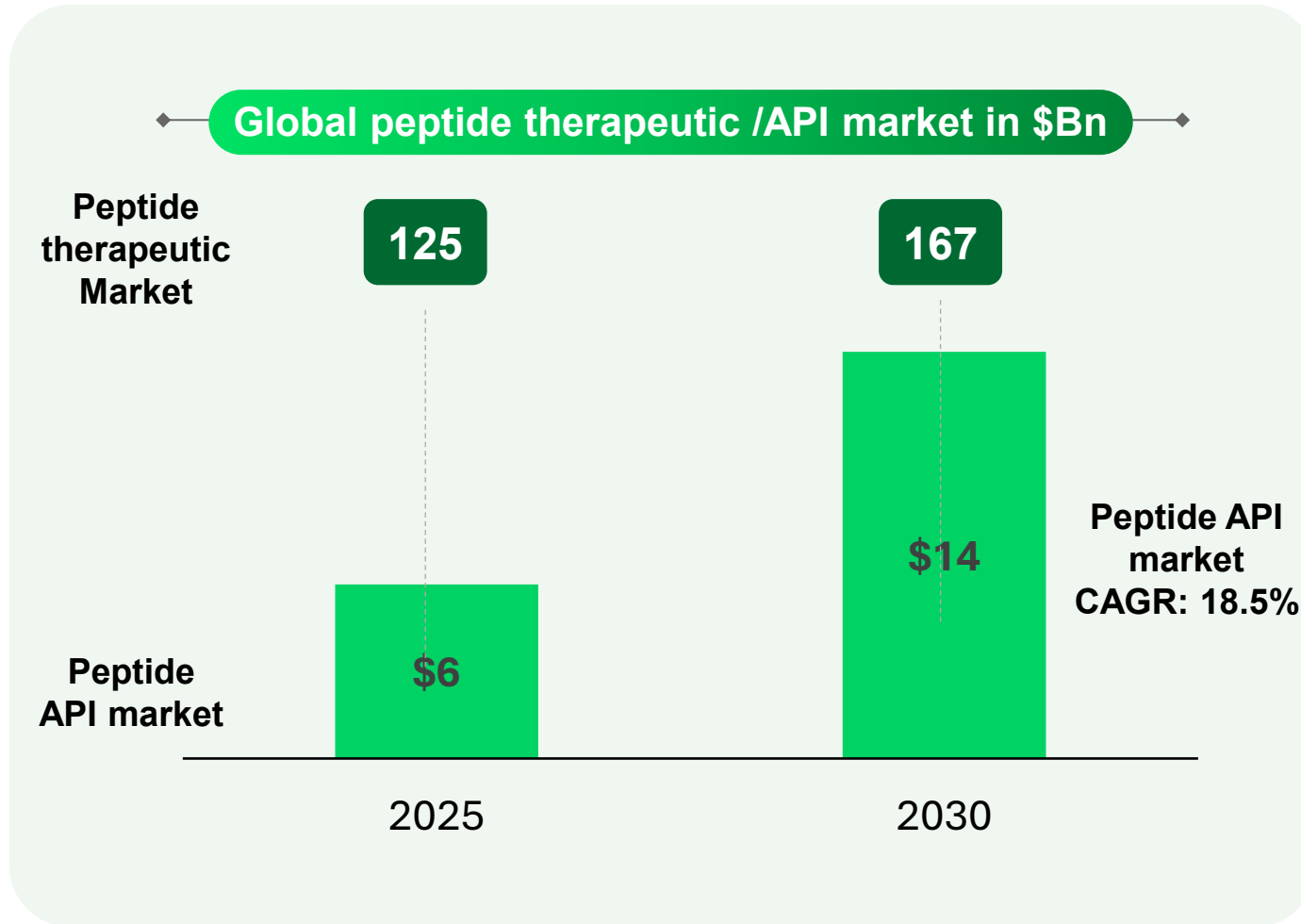
### Empathy

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.**

**Patent cliff of peptides, broadening the availability of these drugs** as volume increases expected to offset price declines



Market size considered based on actual values for the drugs approved by using NDA pathway

GLP-1 - Glucagon like peptide-1

Source data : based on cross tabulation of information from multiple sources,

# Sustainability Framework: ESG commitment & Goals (1/2)



Dimension	Focus area	Our commitments	Key ESG goals (included in Balance Scorecard)
 <b>Environment</b>	Emissions and climate change	Reduce both direct (Scope 1 & 2) and indirect (Scope 3) emissions. Adopt cleaner technologies and improve energy efficiency.	<ul style="list-style-type: none"> <li><input type="checkbox"/> FY 2033-34: 58.8%* reduction in Scope 1 &amp; 2 emissions (FY 2023-24 baseline)</li> <li><input type="checkbox"/> FY 2049-50: Achieve Net Zero in absolute emissions (subject to residual ~10%)</li> <li><input type="checkbox"/> FY 2033-34: 63.8% *reduction GHG emission reductions in indirect Scope 3 emissions (FY 2023-24 baseline)</li> <li><input type="checkbox"/> FY 2049-50: Achieve net-zero emissions across operations and value chain (subject to residual ~10%)</li> </ul>
	Water management	Improve water use efficiency and move toward water neutrality.	<ul style="list-style-type: none"> <li><input type="checkbox"/> FY 2034-35: Achieve 25% water neutrality</li> <li><input type="checkbox"/> FY 2049-50: Achieve 100% water neutrality</li> </ul>
	Effluent and waste	Maintain Zero Liquid Discharge (ZLD) status for our manufacturing operations, reduce solid waste, and ensure 100% co-processing	<ul style="list-style-type: none"> <li><input type="checkbox"/> Maintain Zero Waste to Landfill</li> <li><input type="checkbox"/> 100% co-processing of hazardous waste</li> <li><input type="checkbox"/> Maintain ZLD status of effluents</li> </ul>
	R&D and innovation	Drive sustainable R&D and technology innovation to reduce environmental impact.	<ul style="list-style-type: none"> <li><input type="checkbox"/> Adoption of Green Chemistry and aim to achieve Zero solvent carbon footprint</li> <li><input type="checkbox"/> Commit to annual Life Cycle Analysis (LCA) of 2 molecules per annum from FY 2025-26</li> </ul>
 <b>Social</b>	Occupational health and Safety	Committed to striving Goal Zero in terms of health and injuries	<ul style="list-style-type: none"> <li><input type="checkbox"/> Maintain Zero Fatality</li> <li><input type="checkbox"/> Maintain Nil Long-term Injury</li> <li><input type="checkbox"/> Frequency Rate (LTIFR)</li> </ul>

# Sustainability Framework: ESG commitment & Goals (2/2)



Dimension	Focus area	Our commitments	Key ESG goals (included in Balance Scorecard)
 <b>Social</b>	Diversity and inclusion	Promote equal opportunity and build a more inclusive workplace	<input type="checkbox"/> FY 2029-30: 10% women in management <input type="checkbox"/> FY 2029-30: 16% of all hirings will be women  <input type="checkbox"/> FY 2029-30: 0.5% of employees will be PwD and other genders (LGBTQIA+)
	Community well-being	Support health, education, and livelihood initiatives for underserved communities.	<input type="checkbox"/> Ensure >60% of social impact investments made on well-being of neighboring communities
 <b>Governance</b>	Ethics and compliance	Ensure integrity, fairness, and full legal compliance in all business practices.	<input type="checkbox"/> Ensure systems and processes in place to ensure continued Zero instances of bribery and corruption
	Business Continuity & Risk Management	Build resilience through enterprise-wide risk management, crisis readiness, and business continuity plans.	<input type="checkbox"/> Mature ERM program embracing strategic priorities, emerging risks and resilience
	Digitalisation	Digitise to Enable transparency, Compliance, Speed of decision-making & Ease of doing business, leveraging AI	<input type="checkbox"/> >90% of business process digitised across key functions by 2030
	Sustainable Supply Chain	Build a responsible and transparent supply chain that supports sustainability goals.	<input type="checkbox"/> Create a roadmap for a sustainable supply chain with clearly defined milestones

# 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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