

# **Bharat Parenterals Limited**

Registered Office & Works:

Survey No.: 144-A, Jarod-Samlaya Road, Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.

Mobile: 99099 28332

E-mail: info@bplindia.in, Web.: www.bplindia.in CIN NO: L24231GJ1992PLC018237

(WHO-GMP CERTIFIED ★ STAR EXPORT HOUSE)

Date: November 12, 2025

To, Listing Department

BSE Limited Department of Corporate Services, Phiroze Jeejeebhoy Tower, Dalal Street, Mumbai-400001

**Scrip Code: 541096** 

Dear Sir/Madam,

Subject: Investor Presentation for the quarter and Half Year Ended on September 30, 2025

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find enclosed herewith the Investor Presentation for the quarter and half year ended on September 30, 2025.

Kindly take the same on your record. Thanking You,

Yours faithfully,

For, Bharat Parenterals Limited

Mr. Sharmin Soni Company Secretary & Compliance Officer

M.No: A-75694

**Encl: As above** 



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 or variations 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. Bharat Parenterals Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.



# Standalone key financials highlights

#### **Q2FY26 Financial Highlights (Standalone)**

#### > Revenue from Operations:

Revenue from operations stood at ₹41.7 crore, compared to ₹64.5 crore in Q2FY25 (down 35% YoY) and ₹94.4 crore in Q1FY26 (down 56% QoQ). The decline was primarily due to deferment of export shipments, temporary softness in institutional orders following a strong first quarter, and a nearly one-month production break in the general injectables line owing to ongoing upgradation activity. Management expects volumes to normalise from Q3 onwards as capacity comes fully online and export demand resumes.

#### **EBITDA:**

EBITDA stood at ₹2.3 crore, compared to ₹5.7 crore in Q2FY25 (down 59% YoY) and ₹15.3 crore in Q1FY26 (down 85% QoQ). Lower volumes and capacity utilisation during the quarter led to a decline in operating profit, though fixed-cost controls and a better product mix supported operating efficiency.

#### **EBITDA Margin:**

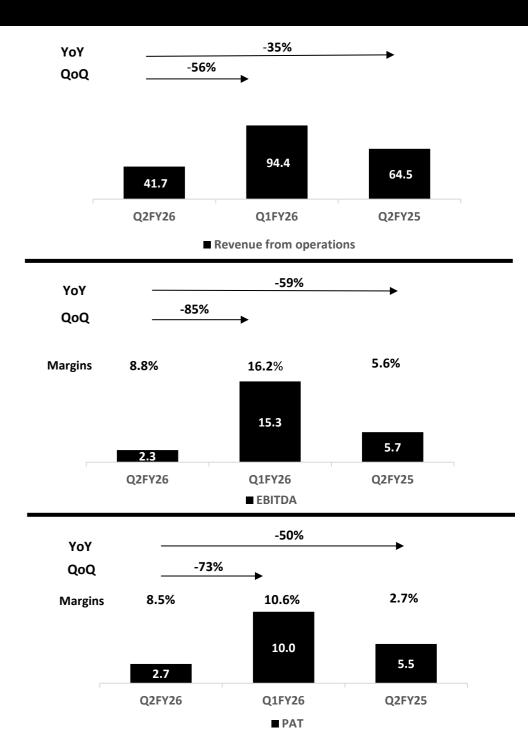
EBITDA margin was **5.6%**, compared to **8.8%** in **Q2FY25** and **16.2%** in **Q1FY26**. Margins were lower sequentially, reflecting reduced throughput, but improved gross margins of 44.1% underscore effective cost management and procurement discipline.

#### ➤ Profit After Tax (PAT):

PAT stood at ₹2.7 crore, compared to ₹5.5 crore in Q2FY25 (down 50% YoY) and ₹10.0 crore in Q1FY26 (down 73% QoQ). Profitability moderated in line with sales, though the Company remained in the black due to sustained operational efficiency and stable overheads.

#### > PAT Margin:

PAT margin was **6.5%**, compared to **8.5%** in **Q2FY25** and **10.6%** in **Q1FY26**. Margins are expected to strengthen in H2FY26 as volumes recover and operating leverage improves with higher institutional and export sales.



## Standalone other highlights

#### **Q2FY26 Other Highlights (Standalone)**

#### > Regulatory & Quality Milestones

- Nigeria (NAFDAC) Audit Cleared: Registration successfully renewed, reaffirming BPL's compliance with African market standards.
- WHO-GMP Certification Renewed:
  - Joint inspection conducted by CDSCO and State FDA authorities.
  - Certification renewed for a further **three years** following a successful audit, reinforcing the company's global quality benchmark.

#### > Product Registrations & Market Expansion

- Ongoing International Growth: BPL continued to strengthen its global footprint with multiple new product registrations across key emerging markets.
- New Market Approvals:
  - Myanmar: 13 products registered through a local distribution partner.
  - Afghanistan: 15 products registered via partner network.
  - Nigeria: 3 products registered and NAFDAC license renewed.
  - Kenya: 2 products approved through partner-led filings.
  - Peru: 2 products registered, expanding presence in Latin America.
  - Vietnam: 1 product registered directly under BPL's own name.
- **Strategic Expansion**: The process has been initiated to set up a representative office in Vietnam, aimed at strengthening BPL's direct presence in Southeast Asia and enhancing regulatory and market access capabilities.

#### ➤ Infrastructure & CAPEX Developments

- General Injectable Vial Line: Upgraded to ORABS standards, enhancing sterility assurance and manufacturing efficiency.
- New Water System: Installed in the Beta-Lactam Block to improve process reliability and product quality.
- Beta-Lactam Block Structural Upgrades: Completed civil and layout modifications to align with EU-GMP compliance ahead of the upcoming audit cycle.

#### Awards & Recognition

BPL Honored with the "Manufacturing SME of the Year – Health & Pharma" Award. Presented by HSBC and CNBC-TV18 under the SME Champion Awards (Season 2) on July 25, 2025, recognizing BPL's excellence in manufacturing, quality, and innovation in the healthcare sector.

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# Financial metrics | Standalone key financials Q1 FY 26

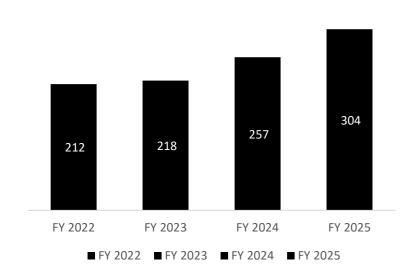
Figures in INR crore

Particulars	Q2 FY 2026	Q2 FY 2025	YOY (%)	Q1FY2026	QOQ (%)	FY 2025	FY 2024	Change (%)
Revenue from operations	41.70	64.45	-35.30%	94.37	-55.81%	304.13	257.98	+17.89%
Other operating revenue	4.21	4.60		1.62		14.55	8.04	
Total operating revenue	45.91	69.05		95.99		318.68	266.02	
EBITDA*	2.33	5.66	-58.83%	15.26	-84.73%	33.59	29.21	+14.99%
EBITDA margin (%)	5.59%	8.78%		16.17%		11.04%	11.49%	
PAT	2.72	5.49	-50.46%	10.00	-72.80%	26.44	22.59	+17.09%
PAT (%)	6.52%	8.52%		10.60%		8.70%	8.89%	
EPS (INR)	3.96	7.90		14.51		40.36	38.97	

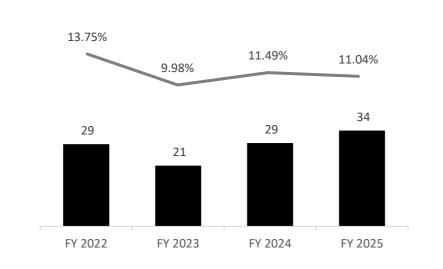
<sup>\*</sup>EBITDA is excluding other operating revenue

# Financial metrics over the years | Standalone

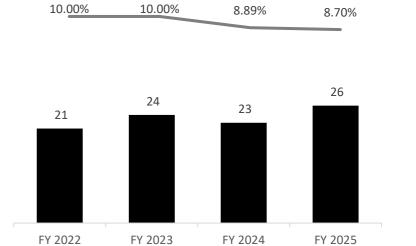
## Total operating revenue (INR crore)



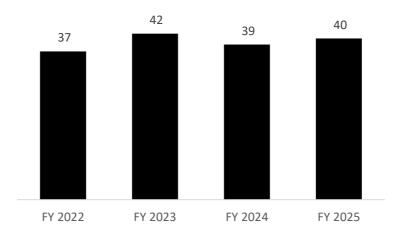
## EBITDA (INR crore and as %)



## PAT (INR crore and as %)



## Earnings per share (INR)



# Consolidated key financials highlights

#### **Q2FY26 Financial Highlights (Consolidated)**

#### > Revenue from Operations:

On a consolidated basis, revenue stood at ₹64.6 crore, compared to ₹71.6 crore in Q2FY25 (down 10% YoY) and ₹116.0 crore in Q1FY26 (down 44% QoQ). The decline was primarily due to lower standalone sales, partially offset by steady milestone income and service revenue from Innoxel Lifesciences.

#### **EBITDA:**

EBITDA turned positive at ₹0.8 crore, compared to a loss of ₹7.7 crore in Q2FY25 and ₹13.8 crore in Q1FY26. The turnaround versus last year reflects better cost control and improved gross margins across subsidiaries, even as sequential performance was impacted by timing of milestone recognitions.

#### **EBITDA Margin:**

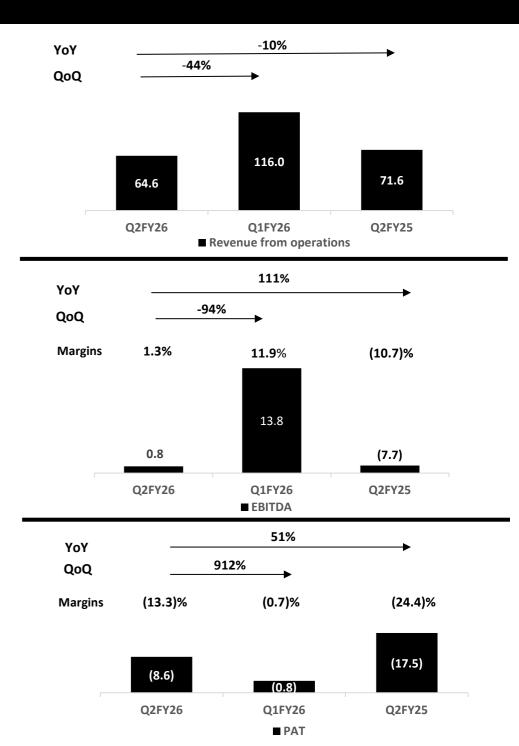
EBITDA margin improved to **1.3%**, compared to **-10.7%** in **Q2FY25** and **11.9%** in **Q1FY26**. The year-on-year improvement demonstrates stronger operational leverage and stabilising costs at Innoxel as it transitions toward the commercial phase.

#### ➤ Profit After Tax (PAT):

Consolidated PAT was a **loss of ₹8.6 crore**, compared to a **loss of ₹17.5 crore in Q2FY25 (improved 51% YoY)** and a **loss of ₹0.8 crore in Q1FY26**. Losses nearly halved year-on-year as Innoxel's cost base stabilised and core operations remained profitable, although sequentially affected by the absence of milestone income.

#### > PAT Margin:

PAT margin stood at -13.3%, compared to -24.4% in Q2FY25 and -0.7% in Q1FY26. The improvement over last year indicates steady progress toward consolidated breakeven as Innoxel approaches key regulatory and commercial milestones.



# Consolidated other highlights

#### **Q2FY26 Other Highlights (Consolidated)**

#### Innoxel Lifesciences Pvt. Ltd. - Q2 Highlights

#### > Regulatory Achievements

**USFDA Approval Secured:** Successfully received the **Establishment Inspection Report (EIR)** for the inspection conducted from **28th April to 2nd May 2025**. The EIR confirms **USFDA-approved status** for the Baroda manufacturing facility, marking a major regulatory milestone and paving the way for commercial supply to the U.S. market.

#### > Business Development & Partnerships

7 New Strategic Deals Finalised During the Quarter:.

- Includes one out-licensing agreement for Innoxel's proprietary product and six new CMO partnerships with leading global companies.
- The cumulative deal value stands at USD 1.85 million, comprising a mix of licensing fees and milestone-linked payments.
- These partnerships further validate Innoxel's technical capabilities in complex injectables and reinforce its positioning as a trusted global CDMO and specialty formulation partner.

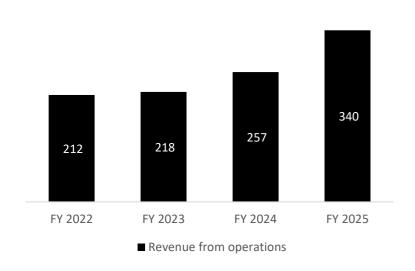
# Financial metrics | Consolidated key financials Q1 FY 26

Figures in INR crore

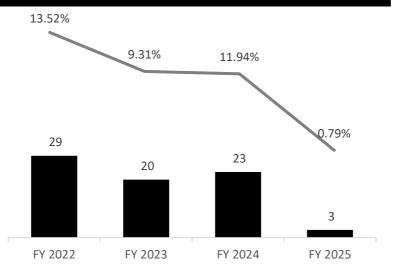
Particulars	Q2 FY 2026	Q2 FY 2025	Change (%)	Q1FY2026	Change(%)	FY 2025	FY 2024	Change (%)
Revenue from operations	64.62	71.63	-9.79%	116.00	-44.29%	304.13	257.98	+17.89%
Other operating revenue	3.53	4.21		1.06		14.55	8.04	
Total operating revenue	68.15	75.84		117.06		318.68	266.02	
EBITDA	0.82	-7.67	+110.69%	13.78	-94.05%	33.59	29.21	+14.99%
EBITDA margin (%)	1.27%	-10.71%		11.88%		11.04%	11.49%	
PAT	-8.60	-17.51	+50.89%	-0.85	-911.76%	26.44	22.59	+17.09%
PAT (%)	-13.31%	-24.45%		-0.73%		8.70%	8.89%	
EPS (INR)	-13.75	-27.30		-1.27		40.36	38.97	

# Financial metrics over the years | Consolidated

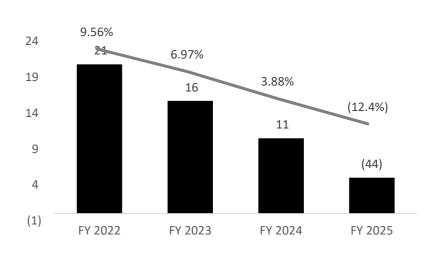
## Total operating revenue (INR crore)



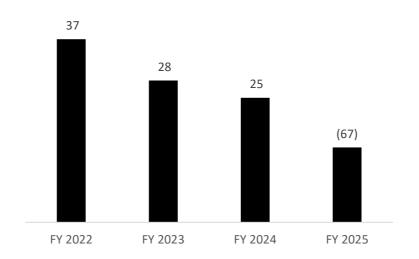
## EBITDA (INR crore and as %)



## PAT (INR crore and as %)



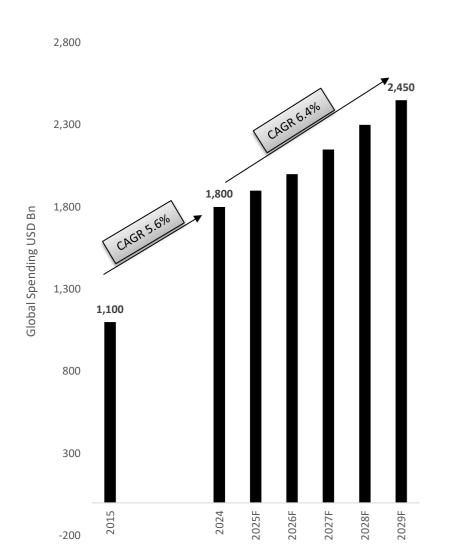
## Earnings per share (INR)





Global medicine spending to reach \$ 2.4 trillion by 2029f with a few key themes having the greatest impact on growth and profitability

#### Global medicine market spending<sup>1</sup>



#### Key themes in the generic finished dosage formulations space

1 GEOGRAPHY FOCUS

Higher growth and stable pricing in emerging markets

NICHENESS OF PORTFOLIO

Superior margins and fewer competitors for niche portfolios

3 BRANDED GENERICS

> Strong brands enjoy stable market shares and pricing power

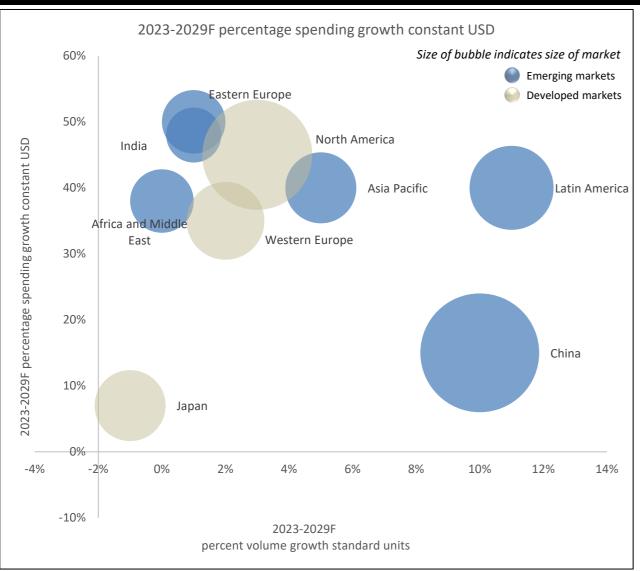
- High volume growth and negligible price erosion in emerging market generics vis-àvis regulated markets
- Evolving regulatory requirements have created entry barriers, reducing competition in emerging markets
- Complex and specialty generics portfolios enjoy substantially higher margins across geographies
- Portfolios backed by innovative technology platforms have greater barriers to entry and fewer competitors

- Established brands command premium prices in emerging markets
- Once established, the market shares of top brands have remained stable over time

Source: IQVIA Market Prognosis, May 2025; IQVIA Institute, May 2025.

Emerging markets expected to experience high growth in spending and volume, while both volume and spending growth to be muted in the developed markets

Population driven volumes and shift towards more expensive medicines because of improved healthcare penetration and rising per capital income will drive emerging market growth trends



Country	Growth trends	Volume and spending growth drivers					
India	High volume growth	Population driven volume growth					
APAC	High spending growth	<ul> <li>Spending growth from a shift in the product mix to more expensive products as healthcare access and</li> </ul>					
Africa & ME	riigii speriuliig growtii	per capita income levels improve					
China	Moderate-high volume growth  Muted spending growth	<ul> <li>Population driven volume growth</li> <li>Muted spending growth as more drugs are added to the NRDL and subjected to price negotiation</li> </ul>					
E. Europe	Low volume growth  High spending growth	<ul> <li>Volume growth hampered by regional disruptions from Ukraine</li> <li>Spending driven by expected adoption of novel¹ drugs</li> </ul>					
W. Europe		Negligible volume growth – stagnant					
N. America	Low volume growth	population/healthcare penetration growth					
Japan	Low spending growth	<ul> <li>Spending growth driven by novel<sup>1</sup> drugs and offset by generic price erosion</li> </ul>					

Source: IQVIA Market Prognosis, May 2025; IQVIA Institute, may 2025.

LATAM: Latin America, E. Europe: Eastern Europe, APAC: Asia Pacific, ME: Middle East, W. Europe: Western Europe, N. America: North America, NRDL: National Reimbursement Drug List.

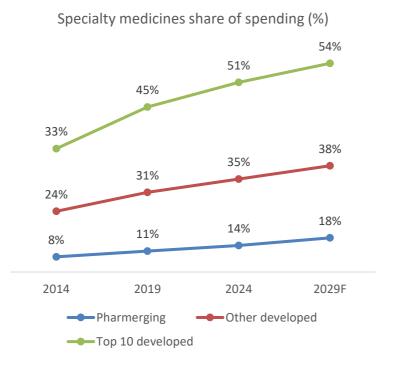
Note 1: Novel drugs are innovative drugs sold under the innovator brand

Branded generics in emerging markets and specialty medicines in developed markets expected to be the most rewarding spaces

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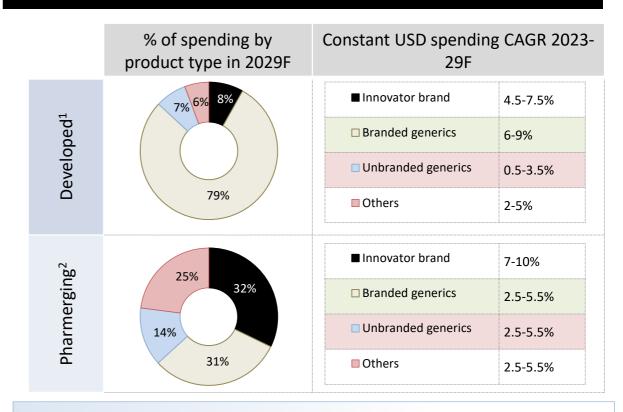
Specialty medicines will be one of the most rewarding spaces in developed markets as the share of spending on them continues to rise

- Specialty medicines are those which treat chronic, complex and rare diseases, and are characterized by complexity in storage, administration, distribution, and high prices
- Specialty medicines can be novel<sup>3</sup> medicines or generics and are usually niche products



- In 2024, specialty medicines accounted for 51% of spending in the top 10 developed countries and 35% in other high and upper-middle income countries—up from 33% and 24% a decade ago.
- Specialty medicines make up 2–3% of volume but a growing share of spending. While they meet critical needs for few patients, costs for traditional therapies are declining.
- Pharmerging countries spent 14% on specialty medicines in 2024, projected to rise to 18% by 2029F, mainly limited by cost

The branded generics segment will be the most attractive in Pharmerging markets



- Wealthier countries spend more on original branded drugs, especially early in patent life
- Lower-income countries rely more on generics and branded generics (copy products).
- Pharmerging countries spend less on originators and more on low-cost generics or non-original brands

Source: IQVIA Market Prognosis, ; IQVIA Institute, May 2025

Note 1: Developed markets are defined based on the World Bank's income definitions and include high and upper-lower-income countries, with the exception of pharmerging markets. Note 2: Pharmerging markets are defined as countries with per capita GDP <\$30,000/year and forecasted 5-year aggregate pharma sales growth >\$1Bn (absolute or rounded) in at least two forecasts. Note 3: Novel drugs are innovative drugs sold under the innovator brand



# The BPL group is built to develop and manufacture FDFs for global markets...

#### Group overview

#### Bharat Parenterals Pvt. Ltd. (listed holding company)

Focus: Export-led pharmaceutical manufacturer of finished

dosage forms (FDFs).

**Key therapies:** Anti-infectives, anaesthesia, pain, CVS

**Key dosage forms:** Injectables, tablets, capsules, eye/ear drops

Key geographies: India, Africa, LATAM, SEA, ME

Standalone

REVENUE FY25: ₹318.7Cr EBITDA FY25: ₹48.1Cr PAT FY25: ₹26.4Cr

Capex FY25: ₹14+ Cr



Particulars	Details			
Location	Vadodara, Gujarat			
Land area	~28,500 sq. mt			
Built-up area	~14,300 sq. mt			
Production area	~4,300 sq. mt			

55.9% subsidiary

#### **Innoxel Lifesciences**

**Focus:** Development and manufacturing of complex/specialty drugs for developed markets

**Key Therapies:** Oncology, pain management, Alzheimer's, long-acting injectibles and liquids

**Pipeline portfolio overview**: 40+ complex products (majority 505(b)(2) and ANDAs); 10+ partnered with global clients

Key geographies: US (majority) and Western Europe

The company is driven by a well-balanced founding team, with 55.9% ownership by promoters and the remaining equity held by experienced technocrats.

100% subsidiary

#### Varenyam Healthcare

Focus: Branded generics for India's institutional market.

**Key Therapies:** Anesthesia, critical care, pain management. Expanding into complex general & oncology injectables (via Innoxel)

**Key Geographies:** Pan-India presence across major hospital chains.

**Team & Strengths:** 180+ on-ground reps across metros and Tier 1/2 cities.

Strong hospital-led channel, not retail/PCD focused.

#### **Varenyam Bio Lifesciences**

100% subsidiary

**Focus:** Manufacturing complex injectables/Specialty Drugs for regulated emerging markets

Acts as a complementary platform to Innoxel, extending global reach

Key Therapies: Complex generics across oncology, long-acting

injectables, NDDS – leveraging Innoxel's pipeline

Key Geographies: Emerging markets

**Pipeline & Strategy:** Will use Innoxel's validated products under royalty-based arrangement. Reduces time-to-market by avoiding repeat development

Facility Status: Under construction; targeted operational

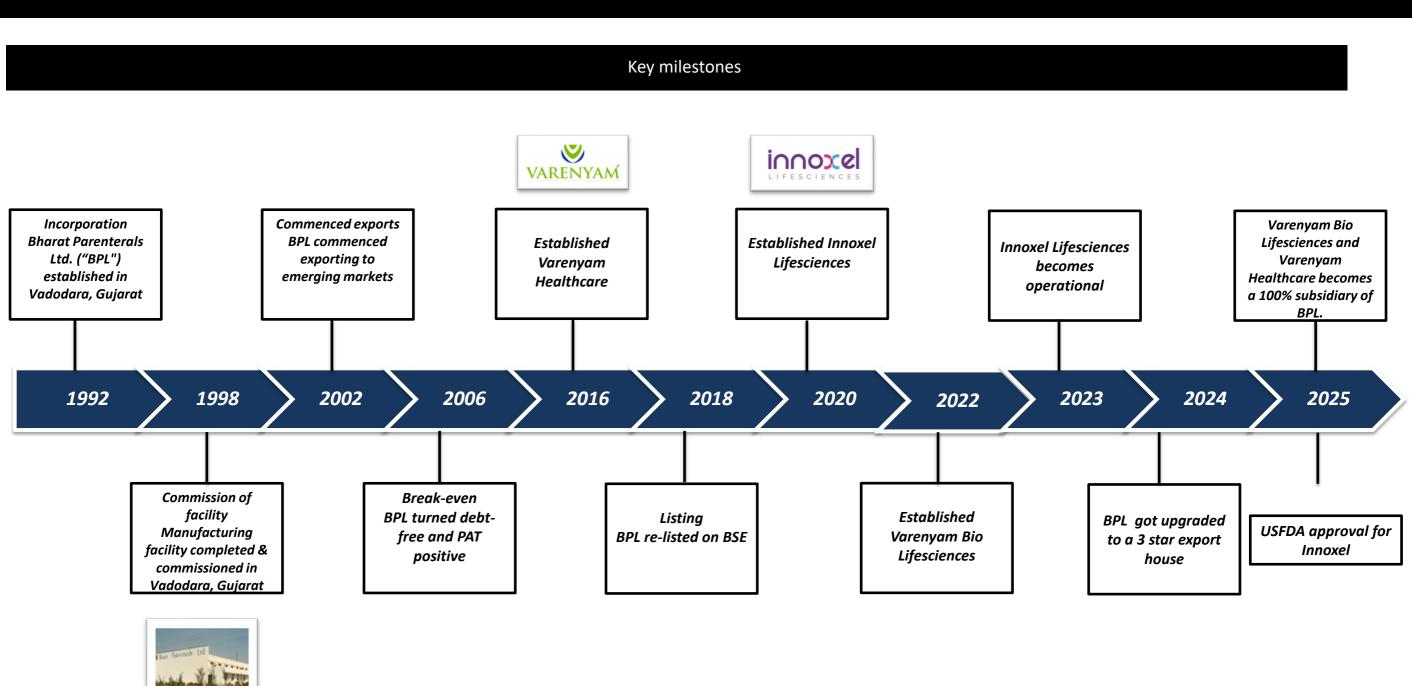
readiness by FY27

Capex till date ~₹30Cr

# Capex ~₹250Cr Facility fully constructed, inspected by USFDA and undergoing product validation

**Minimal Direct Capex** 

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# ...Poised to achieve rapid revenue growth and margin expansion over the next few years...

Solid core business primed for growth and margin expansion

📵 Bharat Parenterals Limited

Deep entrenchment in high-growth geographies enabled by experience of 3+ decades

Regularly upgraded manufacturing facility through the decade

Thoughtfully curated pipeline of product registrations designed to achieve revenue growth and realign product mix to yield higher margins

Promising pipeline driven by world-class R&D with the potential to create a durable, high-margin business



Founding team with the perfect blend of skills to create a regulated market CDMO success story

Supported by a truly state-of-the-art manufacturing infrastructure for the US and EU markets

Differentiated technology platforms with the potential to solve unmet healthcare needs, and a demonstrated track record of commercial success

Strengths across the CDMO continuum to address the complexities of the technology platforms

Promising pipeline that is highly market attuned and leverages the group's experience and expertise

volume and segment



Integration with BPL's manufacturing to drive expansion.

Leveraging complex product portfolio and market access for

continued expansion

Strong presence in top Indian hospitals with proven execution in anesthesia and pain management; first in India to launch Sugammadex

Leveraging BPL's manufacturing and F&D capabilities to enter complex and niche markets within India.

Leveraging Innoxel's complex product portfolio and BPL's market access to achieve further expansion

Expansion into emerging regulated markets using Varenyam Bio infrastructure

# Regulatorily accredited manufacturing infrastructure

#### Product registration pipeline aims to diversify geography mix First-time filings in new countries to New product filings in select existing Region expand presence within the geography countries to deepen presence LATAM Guatemala Ecuador Paraguay Nicaragua Peru Venezuela El Salvador Honduras **APAC Philippines** Uzbekistan Kyrgyzstan Cambodia Nepal Myanmar Afghanistan Vietnam Sri Lanka Africa and ME Ethiopia **Ivory Coast** Uganda Tanzania Zambia Nigeria اله اکبر Madagasca Ghana Kenya Malawi Iraq Mozambique EU Georgia Kosovo

#### Diversification to achieve growth and margin expansion

Growth objective

 Enhanced focus on APAC and LATAM that have higher volume and value growth vs. Africa

Margin expansion objective

Commissioning one new EU GMP compliant blocks

- Across regions, BPL is prioritizing countries where stringent regulatory and compliance requirements have created high entry barriers, resulting in fewer competitors and higher margins
- Post approval these blocks will enable access to several APAC geographies that accept EU GMP compliant manufacturing facilities

#### Regulatory accreditations



























# ...Therapy area focus, and product mix

Therapy area	Sound strategy guiding therapy are	a-wise objective	Thoughtfully designed product registration pipeline			
merapy area	Strategy	Current	pipeline			
Anti-infectives	<ul> <li>Anti-infectives are competitive spaces with moderate margins</li> <li>BPL plans to shift focus away from anti-infectives into other categories</li> <li>Realign focus to select higher-margin products</li> </ul>			<ul> <li>BPL has selectively filed newer classes of antibiotics like Tigecycline,         Tazobactam, and other niche anti-infectives</li> <li>Limited filing of older generation anti-infectives</li> </ul>		
Critical care	<ul> <li>Injectable products in this category have few competitors and higher margins</li> <li>BPL plans to expand presence and increase revenue contribution from this portfolio</li> </ul>			<ul> <li>Renewed focus on critical care products like Bupivacaine, Lidocaine, Atracurium Besylate with filings of these products in new geographies</li> <li>Filed higher-margin anaesthesia products like Sugammadex</li> <li>Filed higher-margin pain products like Tramadol and Pentazocine</li> </ul>		
Others	Enter niche products with higher margins across a variety of therapeutic categories to replace anti-infectives		<b>&gt;</b>	Filed higher-margin products in CNS (Fluphenazine Decanoate) and CVS (Glyburide + Metformin)		

Size of the bubble denotes revenue share. Not to scale

# Innoxel at a glance

# Innoxel is an innovation-driven, regulated market CDMO with their own product portfolio of specialty generics

#### **Snapshot**

- Overview:
- > Innoxel is a regulated market focused, specialty FDF CDMO.
- > Engaged in the development, manufacturing, and partnering of complex dosage forms, 505 (b)(2)s, and other specialty products
- Primary markets: US and Europe

#### Portfolio overview

Innoxel's portfolio provides solutions for unmet healthcare needs, and has been built around an identified set of differentiated technology platforms, which leverage the founding team's experience and expertise



- Capacity of 6 mn vials p.a.1
- Expandable to 14 mn p.a. per line (General and potent lines)



- Capacity of 3 mn bottles p.a.<sup>2</sup>
- Expandable to 6 mn p.a. per line (General and potent lines)

#### **Business segments**

Portfolio of own products which have been outlicensed to front-end marketing partners for milestone payments + transfer revenues + profit share

CMO contracts with innovator and generic large pharma, yielding conversion-cost-based revenues

#### Capabilities and capacity

Oral liquid formulations



Liposomal injectables



Extended release injectables



#### Infrastructure



Located in Vadodara with a total manufacturing area of 350,000 sqft



2 manufacturing blocks

Block 1 - General manufacturing Oral liquids in bottles and injectable vials

Block 2 - Oncology manufacturing Oral liquids in bottles and injectable vials

#### Planned regulatory approvals



Received EIR (Establishment Inspection Report) on 30<sup>th</sup> July 2025 enabling commercialization



Regulatory inspection anticipated by Q3 FY26

- · India's only US FDA approved **Oncology Oral Liquid** manufacturing facility, and one of only six globally.
- · One of the few SKID manufacturing facilities in India.

# Business segment overview

Innoxel has two business segments with revenues from manufacturing, milestone achievements, and profit share from clients and partners

Segments		Own products	СМО			
Description	<ul> <li>Innoxel identifies and carries out product development up to a certain stage, after which it is out-licensed to a front-end partner who will fund the product through to filing and approval.</li> <li>Partner owns the NDA/ANDA/MA and will be responsible for front-end-marketing.</li> <li>Innoxel will be the exclusive manufacturer for the product</li> </ul>		<ul> <li>Innoxel manufactures the product for their client, providing manufacturing support from the clinical trial stage to the commercial manufacturing stage.</li> <li>One of the only India-based formulation CMOs working with Innovator clients for their novel molecule</li> </ul>			
	Manufacturing  Revenue (at an agreed upon transfer price) from contract manufacturing of products for front-end partner		Manufacturing	Revenue based on conversion cost per batch of manufacturing for outsourcing client		
Revenue streams	Milestones	Revenues tied to completion of clinical and product development milestones	Milestones	Revenues tied to completion of clinical and product development milestones		
	Profit share	Profit share Pre-determined share of front-end partner's profits after accounting for transfer cost and marketing costs				
No of products	more are in variou	ned partnerships for 12 products with a front-end partner, while 20 us stages of development. Going forward, we plan to add 5–6 ar to achieve a diversified portfolio of 40+ products.	10 CMO contracts id	entified and signed. Several others in pipeline		
Client type		specialty generic companies with strong front-end presence in the ack record of successfully marketing specialty products		novator pharma companies requiring regulatorily approved city for complex products		

# nnoxe

### Pillars of a regulated market CDMO success story

Operational excellence

Mr. Bharat Desai



30+ years at Holdco managing a large injectable manufacturing company

Work experience:





 B.Sc (Chemistry) from SP University Differentiated R&D skills

Dr. Manish Umrethia



CEO of Auxilia Pharma, an R&D and formulation development company

Work experience:







- B.Pharm, M.Pharm (LMCP, Ahmedabad)
- Ph.D. (MS University of Baroda)
- Post Doctoral (Queens University, Belfast)

Sound strategic direction

Mr. Bhahim Desai



Managing Director of Varenyam Healthcare Pvt. Ltd, a domestic branded formulations company

Work experience:





- B.Pharm
- MBA in Pharmaceutical Marketing and Management, NMIMS, Mumbai

Wide clinical experience

Mr. Manoj Vyas



CEO of CBCC Global Research, a Contract Research Organisation based out of US and India

Work experience:



- M.Sc. Chemistry (Gujarat University)
- Masters Clinical Research (Cranfield University, UK)

Robust regulatory & compliance

Mr. Tushar Patel



CEO of Pharmazone, a provider of regulatory affairs and compliance advisory services

Work experience:



- B.Pharm. (LMCP, Ahmedabad)
- Masters Clinical Research (Cranfield University, UK)

Deep commercial networks

Mr. Manoj Bharathi



Director of GeneriQ
Pharmaceuticals, a
commercial licensing advisory
firm

Work experience:



- B.Tech .Chemical Engineering (Anna University, Chennai)
- MBA (IIFT, Delhi)

# ...With the ability to formulate solutions for unmet healthcare needs...

Category	Drug characteristics		Impact	
	The encapsulated drug is protected from rapid degradation and elimination by the body	Ø		
	The drug circulates in the body for longer, allowing for modified drug release profiles (sustained/controlled)	Ø		
	Usually manufactured with naturally derived starting materials. Offer excellent biocompatibility and safety and fewer side effects		6	
Liposomal	Allow for targeted delivery of drug to site of disease and improved bioavailability. This improves therapeutic benefits and causes fewer side effects	Ø	6	
injectables	Well-suited for oncology			
	Liposomal injectables are lipid-based drug vesicles with one or more bilayers enclosing an aqueous compartment.			
	They can carry a hydrophilic drug in the aqueous compartment and a hydrophobic drug between the bilayers			
	Lower dosage frequency which reduces discomfort and enhances patience convenience			
	Ability to target specific anatomical sites in the body where high drug concentrations can be maintained. This improves therapeutic benefits and causes fewer side effects	Ø	<b>6</b>	
Extended release	Improved patient compliance	Ø		
injectables ("ER")	Allows for consistent levels of drugs in the body - fewer side effects and improved therapeutic benefits	Ø	<b>6</b>	
	Well-suited for CNS disorders, chronic pain, hormonal contraception, and oncology			
	• Extended release injectables are parenteral, sustained drug delivery systems which are injected into the body and then slowly released over a long period of time (typically 2-12 weeks)			
	Oral liquids are absorbed more quickly compared to oral solids	Ø		
Oral solid to	Convenience and comfort to pediatric and geriatric populations that struggle with swallowing solid orals		6	
liquid conversion products	Offer dosing flexibility. Simple and convenient to change the dosage in case of medicines requiring complex dose titration/adjustment based on body weight	Ø		
products	Well-suited for anti-hypertensives and CNS disorders			
Other products	Ready to use injectables ("RTU")			
with high barriers to entry	Products with clinical complexity requiring patient based clinical trials (usually, generic product trials are carried out on healthy patients).			
	Formulations with APIs that are difficult to source			

# Well-hedged against all types of risk through leverage of strengths across the CDMO continuum

Risks	Description	Innoxel's hedge
Development risk	<ul> <li>Inability to successfully complete formulation development/achieve clinical objectives in a timely manner</li> </ul>	<ul> <li>Dr. Manish has led the development of over half the currently marketed liposomal injectables</li> <li>Dr. Manish has 50 patents to his name as a lead scientist and 40+ formulations in developed and developing market.</li> </ul>
Clinical trial risk	<ul> <li>Delay in obtaining slots with a clinical trial services provider, patient recruitment, formulation of study design and protocol</li> <li>Risk of cost and time overruns</li> </ul>	<ul> <li>The waiting period for clinical trial slots for Innoxel will be lower by 8-10 months due to its affiliation with CBCC, helping them avoid delays and cost overruns</li> </ul>
Filing and approval risk	<ul> <li>Inability to make complete filings, delays in approval resulting from issues in communication</li> </ul>	<ul> <li>Mr. Tushar and CBCC's combined expertise and experience in managing regulatory affairs and FDA communications</li> <li>Dr. Manish's experience with filing similar products</li> </ul>
Commercialization risk	Inability to generate demand and win market share	<ul> <li>The portfolio has been curated to ensure that it caters to clear unmet patient needs</li> <li>Mr. Manoj's experience with finding the right licensing partners, who have the access and expertise necessary to commercialize the product and win market share</li> </ul>
Infrastructure/ Regulatory risk	Receipt of adverse feedback by regulatory authorities post facility audit	<ul> <li>Innoxel to leverage the experience of Mr Tushar, who is a seasoned GMP consulting professional</li> <li>Operational aspects of the company to be overseen by the Holdco leadership team</li> </ul>









Development

BA/BE studies

ANDA/ NDA filing

Commercial manufacturing

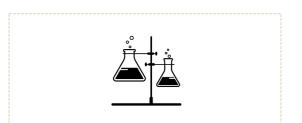
Complexities / Barriers to entry  Level of formulation and analytical characterization data required by USFDA is very complex  Complex BA/BE studies where a close match must be established with the reference drug across several parameters  Usually filed through the ANDA route, however the process is much more complex compared to plain injectables

- Scale up and manufacturing require procurement and installation of product specific manufacturing SKIDs
- SKIDs have an installation lead time of 9-12 months and require a USD 6-8 mn investment

Project Blue's strengths

- Dr. Manish's experience in leading successful liposomal injectable generic programs for Sun Pharma
- Other key personnel have handled tech transfer and manufacturing of such programs at Sun, DRL etc.
- Mr. Manoj V's experience with running large trials for complex liposomal injectables
- Dr. Manish and Tushar's experience with filing successful ANDAs for liposomal injectables and corresponding with the USFDA to clarify all analytical and characterization approaches
- Facility built to accommodate SKID units for multiple products
- Components of planned SKIDs have been identified from specialist vendors (in India and Europe) and layout has been designed

Complexities









### Development

#### Clinical work

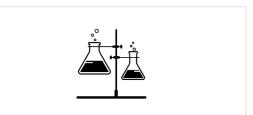
### ANDA/ NDA filing

# Commercial manufacturing

- Absorption characteristics of the drug at the injection site and stability during the dosing interval must be precise
- Source/develop device for delivering highly viscous drugs
- Properties such as zeta potential, rheology, particle size distribution are critical parameters that determine manufacturing success.

- 505 (b)(2) filings require extensive clinical trial work
- Filing must not infringe on the significant intellectual property and trade secrets protecting ER injectables
- Usually filed through the 505 (b)(2)
   NDA route which is more expensive and complex than ANDAs
- Scale up and manufacturing require procurement and installation of product specific manufacturing SKIDs

- Dr. Manish's experience successfully developed a highly complex drug device combination for a very viscous product at Auxilla (1bn USD product with only 1 generic approved)
- Dr. Manish and Tushar's experience with putting together comprehensive Pre-IND meeting packages and designing optimized clinical plans and corresponding with the USFDA, to take their inputs on it
- Mr. Manoj V's experience with running large trials in oncology, neuropsychiatry in a cost and time efficient fashion
- Project Blue's products are noninfringing to currently existing patents in the selected space.
- Dr Manish and Tushar's experience and understanding of the filing process and USFDA expectations
- Facility built to accommodate SKID units for multiple products
- Components of planned SKIDs have already been identified from specialist vendors (in India and Europe) and layout designed











Development

BA/ BE/PK studies

ANDA/ NDA filing

Commercial manufacturing

Complexities

 Right excipients must be identified and incorporated into development to achieve the desired bioavailability and absorption.  For oral solid to liquid conversions, optimum data and relevant precedents need to be discussed with the USFDA to finalize a cost and time efficient clinical pathway via the BA/BE or a patient-based PK approach.  Usually filed through the 505 (b)(2)
 NDA route which is more expensive and complex than ANDAs  USFDA / EUGMP compliant potent liquid manufacturing capabilities are a rarity globally.

Project Blue's strengths

- Dr. Manish has worked on 40+ first time oral solid to liquid conversion products over the past 5 years with multiple approved products.
- He led development for 4 out of the 5 oral liquids approved by USFDA in 2023
- Dr. Manish's experience with designing and executing bioequivalence/PK studies for 40+ first time oral solid to liquid.
- Mr. Manoj V's experience with running multiple trials in this area.
- Dr Manish and Tushar's experience and understanding of the filing process and USFDA expectations
- USFDA/EUGMP compliant oncology/potent liquid manufacturing line and setup in place

# Varenyam Healthcare is a high-impact speciality branded generics business.

#### Overview

Established in 2016, Varenyam Healthcare is a specialty pharmaceutical company focused on critical care, anesthesia, and pain management.

Presence in 7,500+ hospitals across India, supported by a 180+ person field force.

Strong presence in top institutional chains including Apollo, NH, Fortis, Manipal to name a few.

Products aligned with BPL's manufacturing, enabling better control over quality, speed, and margin.

#### **Products**

Portfolio includes high-quality injectables tailored for hospital-driven therapies.

First in India to launch Sugammadex 100 mg/ml (anaesthesia reversal) in JV with BDR Pharma.

FoQas – time–temperature indicator to ensure cold-chain compliance for sensitive products.

Pipeline includes complex general and oncology dosage forms in upcoming launches.



## **Strategy & Differentiators**

Deep institutional presence with focused therapeutic strategy and a skilled sales force.

Growth via expanding portfolio and tapping into complex formulations using BPL/Innoxel's R&D.

Launching two new therapeutic divisions over next 2–3 years.

Plans to scale revenue to ₹100 Cr by FY28.

#### PRODUCT PORTFOLIO

Leverages Innoxel's & BPL's R&D pipeline through inlicensing, reducing time-to-market and avoiding repeat development.

Focused on complex dosage forms (injectables, long-acting formulations, oncology, NDDS, Lyophilized injectables).

Designed to repurpose and relicense Innoxel's 505(b)(2) and complex ANDA portfolio for high-growth, underpenetrated markets.

Varenyam Bio

Lifesciences

#### Overview

Incorporated in 2022, Varenyam Bio is a strategic extension of the BPL group focused on manufacturing complex injectables and oral liquids for regulated emerging markets.

Created to complement Innoxel Lifesciences by serving countries outside the US/EU, including those requiring higher regulatory approvals.

Facility will target EUGMP and local regulatory approvals across LATAM, Africa, Eastern Europe, and Australia.

### Strategy & Infrastructure

Offers rapid entry into Tier 2 global markets through localized regulatory strategies.

Lower-cost execution model with faster monetization than highly regulated CDMO pathways.

- 2 Particulate injectable lines: general and potent
- 2 Lyophilized injectable lines: general and potent

### Outlook

#### **FY26E Financial Outlook**

- ➤ BPL (Standalone): The Company remains confident about its growth trajectory, maintaining FY26 revenue guidance of 12–14%, supported by a strong order book, expanded distribution footprint, and better capacity utilisation. EBITDA margins are expected to improve to 15–17%, driven by operating leverage and an increased share of institutional business.
- ➤ Innoxel: Innoxel is expected to generate ₹65–70 crore in revenue in FY26, with a stable quarterly cost base of ₹15–16 crore. The business is poised to achieve operational break-even through milestone-driven product revenues. Commercial CMO supplies are anticipated to commence in Q1 FY27, following the scheduled EU-GMP inspection in FY26.
- ➤ Varenyam Healthcare: Revenue for Varenyam is projected at ₹60–65 crore in FY26, marking a 20–21% year-on-year growth. Expansion into new therapeutic areas and increased penetration in existing segments will continue to fuel momentum in the domestic business.