Bharat Parenterals Limited

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CIN NO: L24231GJ1992PLC018237
(WHO-GMP CERTIFIED ★ STAR EXPORT HOUSE)

DATE: 20TH FEBRUARY, 2024

To,
BSE Limited,
P.J. Towers,
Dalal Street,
Mumbai – 400001.

Ref.: Company Code: 541096

Dear Sir/Madam,

SUB: INVESTOR'S PRESENTATION_FEBRUARY 2024.

In compliance of Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we are pleased to enclose the investor presentation titled "*Investors presentation_ Feb, 2024*". This presentation provides comprehensive information regarding outlook of the Company and Subsidiary Business based on Financial Result disclosed on 13th Feb, 2024. The investor presentation, which we shall be uploading on our website after sending this letter to you.

Request you to please take the same on record.

Thanking You,

FOR BHARAT PARENTERALS LIMITED,

KRUTIKA BHATT BHATT

BHARAT PARENTERALS LIMITED VADODARA

Bharat Parenterals Limited

Disclaimer

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.

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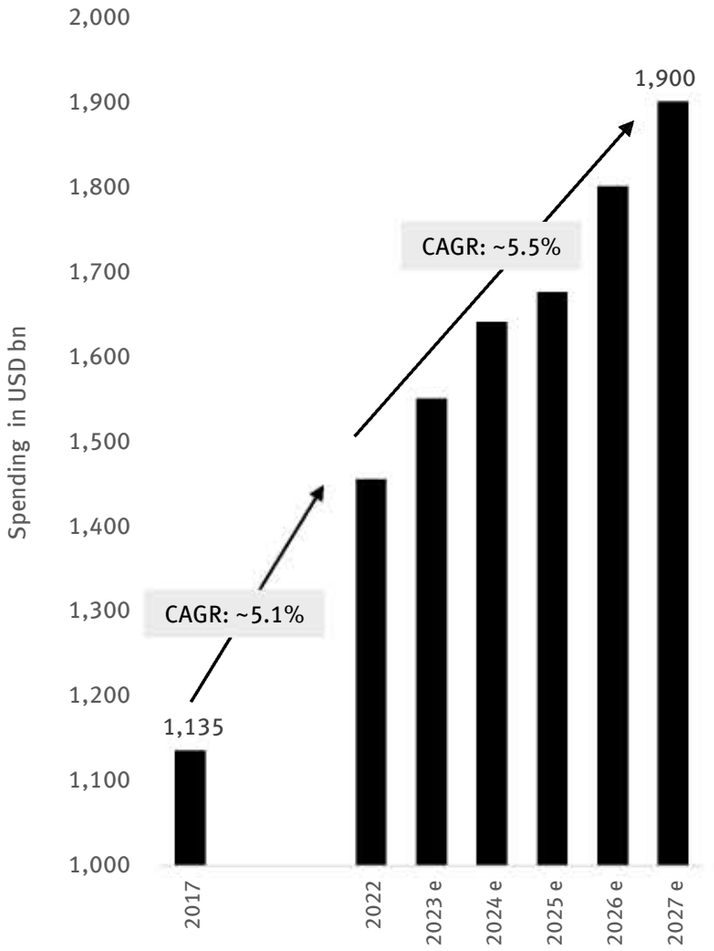
Market overview

Global medicine spending to reach $ 1.9 trillion by 2027 with a few key themes having the greatest impact on growth and profitability

Global medicine market spending[1]



Key themes in the generic finished dosage formulations space

1 **GEOGRAPHY FOCUS**

Higher growth and stable pricing in emerging markets

- **High volume growth** and **negligible price erosion** in **emerging market** generics vis-à-vis regulated markets
- **Evolving regulatory requirements** have created **entry barriers**, reducing competition in **emerging markets**

2 **NICHENESS OF PORTFOLIO**

Superior margins and fewer competitors for niche portfolios

- **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

3 **BRANDED GENERICS**

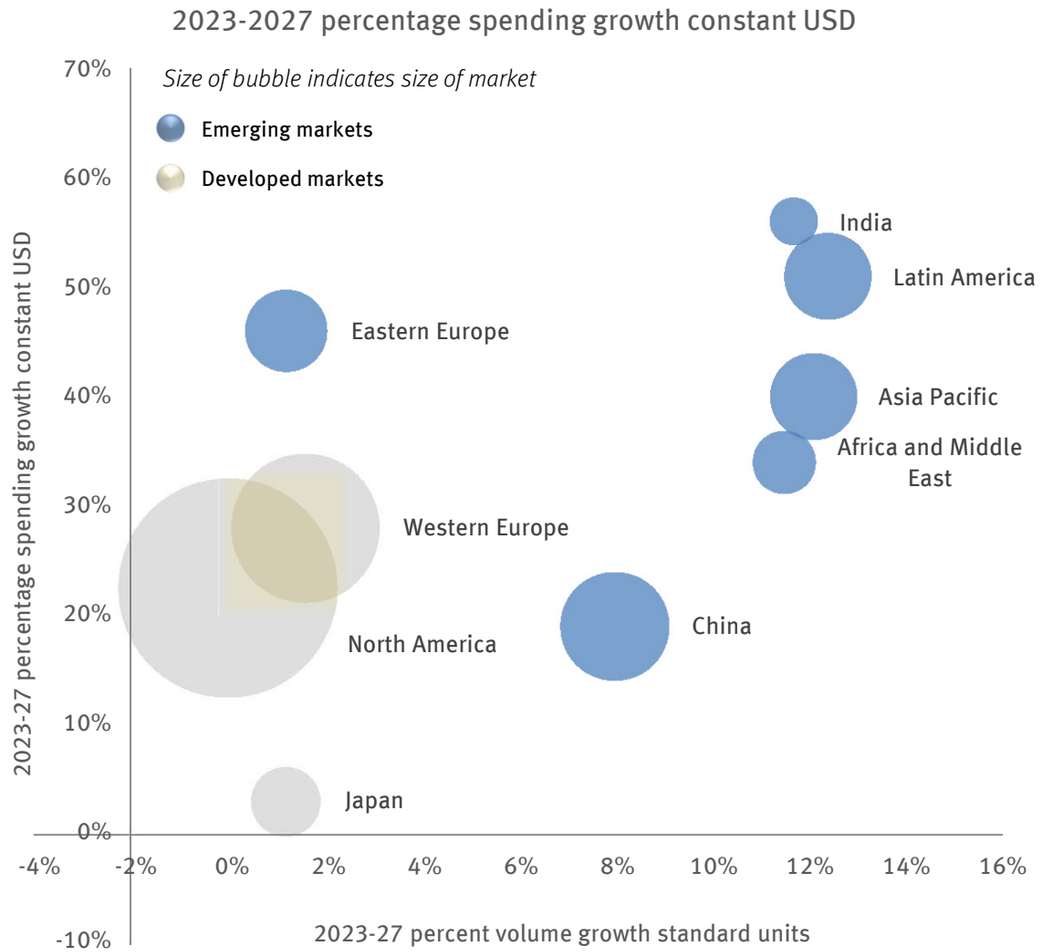
Strong brands enjoy stable market shares and pricing power

- 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, Sep 2022; IQVIA Institute, Nov 2022.
Note 1: Measures the amount spent purchasing medicines from manufacturers before off invoice discounts and rebates, and excludes the impact of spending on COVID 19 vaccines and therapeutics

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

1 **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**



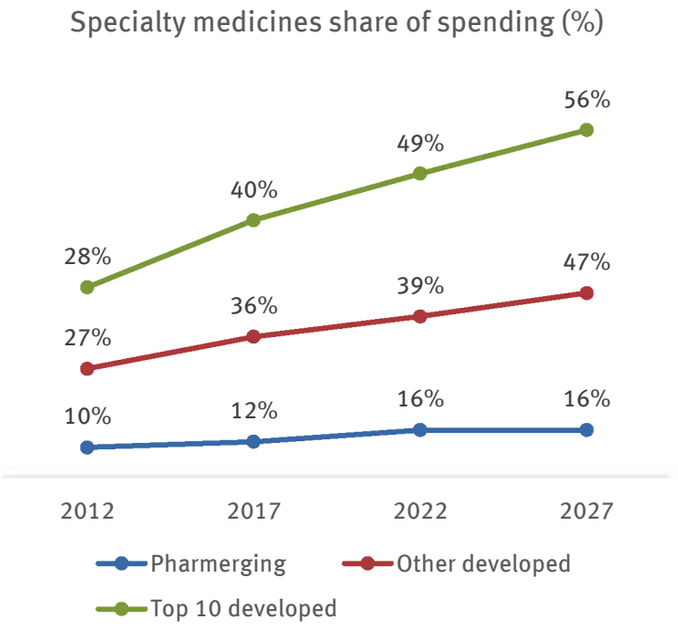
Country	Growth trends	*Volume and spending growth drivers*
India, LATAM, APAC, Africa & ME	High volume growth / High spending growth	• **Population driven** volume growth • Spending growth from a **shift** in the **product mix** to more **expensive** products as **healthcare access** and **per capita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

Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
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

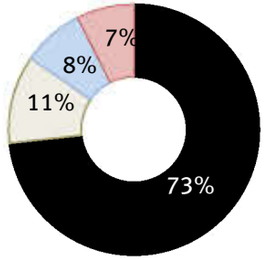
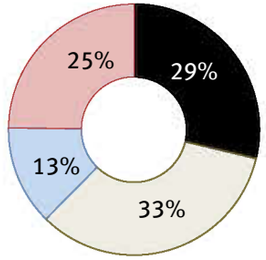
2 Specialty medicines will be one of the most rewarding spaces in developed markets as the share of spending on them continues to rise

- *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[3] medicines or generics and are usually niche products*



- Specialty medicines have been **increasing as a share of spending** in developed markets – a trend that is **expected to continue**.
- Specialty medicines are **expensive and treat ~1-2% of patients.** They have **resisted** the **price erosion** faced by traditional therapies
- Pharmerging market share of spending on specialty has lagged due to cost/affordability

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

	% of spending by product type in 2027e	Constant USD spending CAGR 2023-27e	
Developed[1]		Innovator brand	3-6%
		Branded generics	5-8%
		Unbranded generics	-1-2%
		Others	0.5-3.5%
Pharmerging[2]		Innovator brand	5-8%
		Branded generics	5-8%
		Unbranded generics	4.5-7.5%
		Others	5-8%

- Developed markets spend on innovator brands while Pharmerging markets are focused on generics
- Branded generics will see the **highest growth** across markets and **resist price erosion**
- **Unbranded generics** face **price erosion** in developed/regulated markets and display **slower growth** in spending in the Pharmerging markets

Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
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

Group overview

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

Key milestones

Group overview

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

Manufacturing formulations for emerging markets

Key therapies: Anti-infectives, anesthesia, pain, CVS

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

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

51% subsidiary

60% subsidiary (process underway to convert to 100% subsidiary)

Innoxel Lifesciences

Development and manufacturing of complex/specialty drugs for developed markets

Pipeline portfolio overview: Extended release injectables, particulate injectables, ready to use injectables, oral liquids, and 505 b(2)s in the areas of oncology, Alzheimer's, and pain, etc.

Key geographies: US (majority) and Western Europe

Varenyam Bio Lifesciences

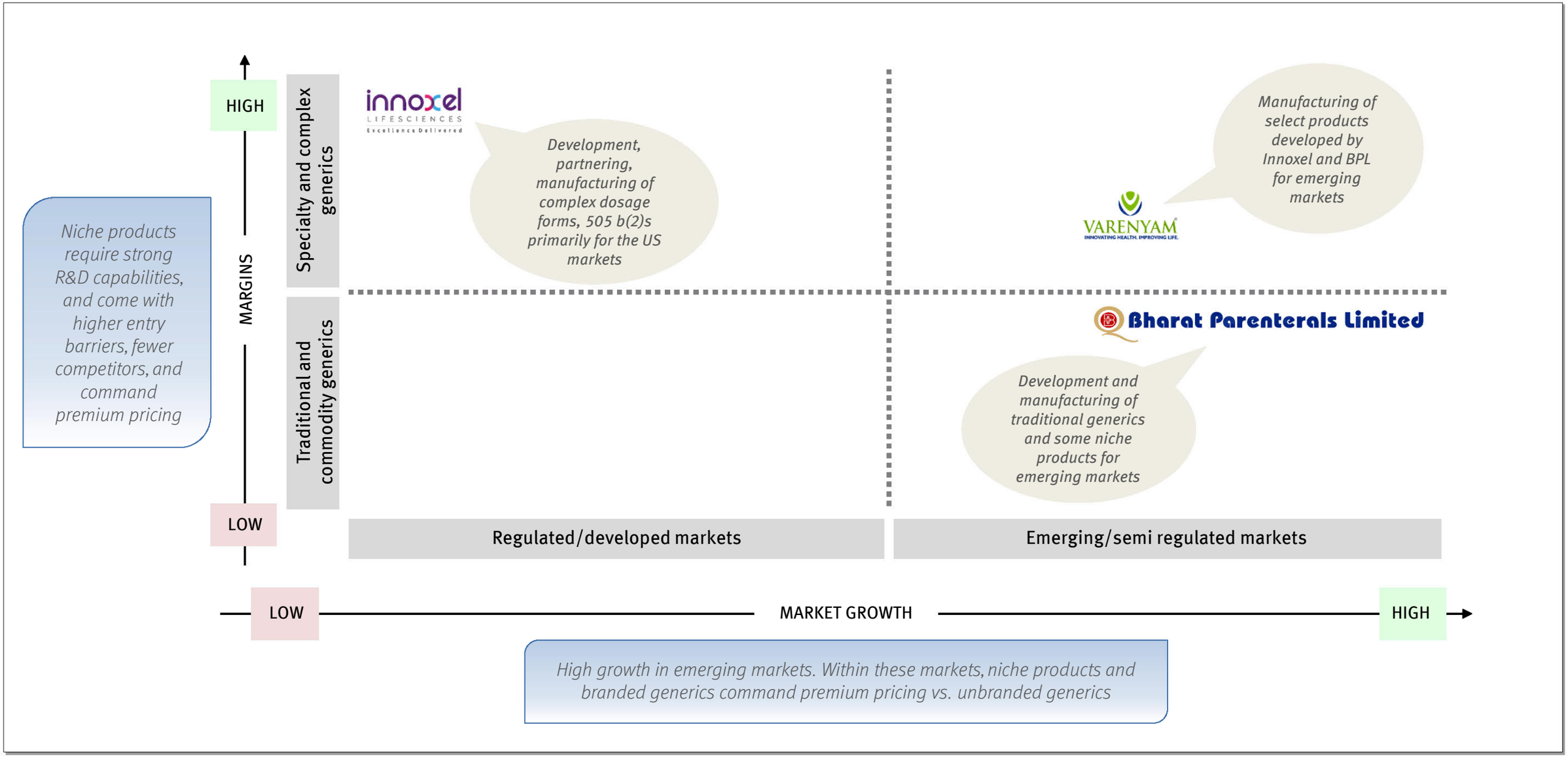
Manufacturing complex/specialty drugs for emerging markets

Pipeline portfolio overview: Complex drugs across dosage forms and therapy areas

Key geographies: Emerging markets

FDF: Finished Dosage Formulations, CVS: Cardiovascular, PAT: Profit after tax, LATAM: Latin America, SEA: South East Asia, ME: Middle East, US: United States of America

...with a presence spanning the most attractive spaces in the global FDF market...



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

Bharat Parenterals

Innoxel

Varenyam Bio

1

Solid core business primed for growth and margin expansion

Bharat Parenterals Limited

- *Deep entrenchment in high-growth geographies enabled by experience of 3+ decades*
- *Regulatorily approved manufacturing and R&D infrastructure*
- *Thoughtfully curated pipeline of product registrations designed to achieve revenue growth and realign product mix to yield higher margins*

2

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

innoxel LIFESCIENCES Excellence Delivered

- *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*
- *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*

3

Leveraging complex product portfolio and market access for continued expansion

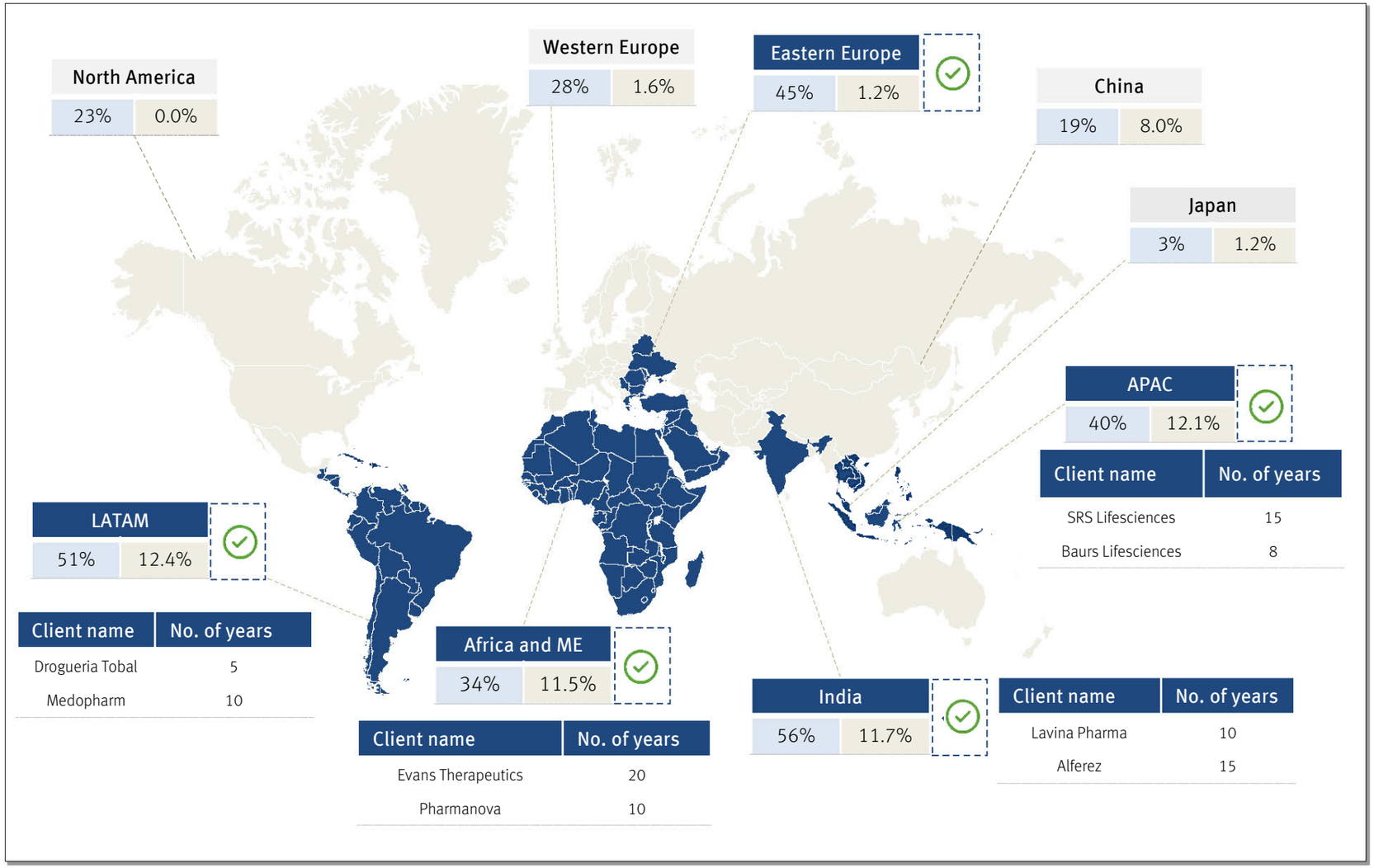
VARENYAM INNOVATING HEALTH, IMPROVING LIFE

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

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

Bharat Parenterals | Innoxel | Varenyam Bio

BPL enjoys long-standing presence and commercial relationships in high-growth geographies



North America	
23%	0.0%

Western Europe	
28%	1.6%

Eastern Europe	
45%	1.2%

China	
19%	8.0%

Japan	
3%	1.2%

APAC	
40%	12.1%

Client name	No. of years
SRS Lifesciences	15
Baurs Lifesciences	8

LATAM	
51%	12.4%

Client name	No. of years
Drogueria Tobal	5
Medopharm	10

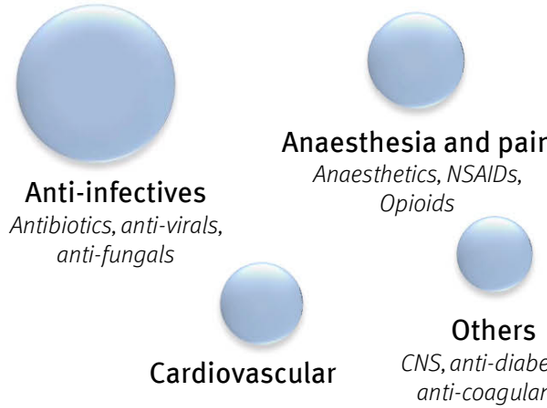
Africa and ME	
34%	11.5%

Client name	No. of years
Evans Therapeutics	20
Pharmanova	10

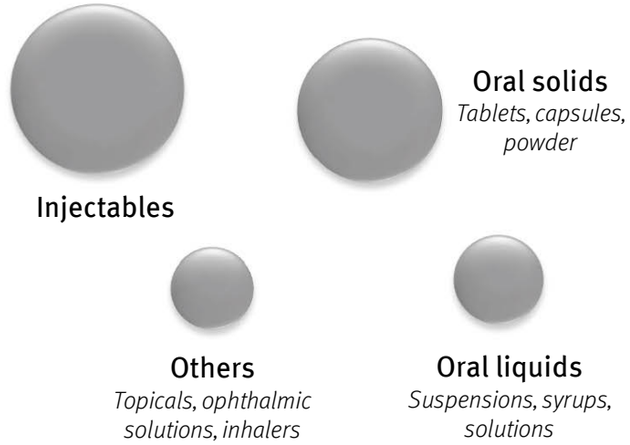
India	
56%	11.7%

Client name	No. of years
Lavina Pharma	10
Alferez	15

BPL's therapy area focus



BPL's dosage form focus



2023-27 market spending growth (constant USD) | 2023-27 market volume growth (standard units) | Bharat Parenterals Ltd. presence

Size of the bubble denotes revenue share. Not to scale

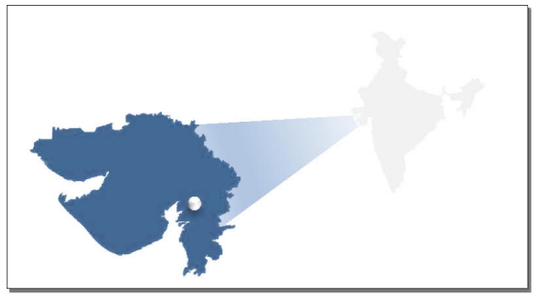
Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022. No. of years indicates length of BPL's relationship with the client

1 Regulatorily accredited manufacturing infrastructure

Bharat Parenterals

Innoxel

Varenyam Bio



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

Key infrastructure

- 3 independent and dedicated production blocks: General, Beta Lactam, and Cephalosporin
- Separate service floor for all sections to minimize personnel movement across sections and reduce probability of contamination
- Separate air handling units for each section for air conditioning and dehumidification as per product requirements
- Adequate water systems: purified water and water for injection with zero dead leg and in hot re-circulation loop
- Formulation and Development Department has been recognized by the Department of Scientific & Industrial Research (DSIR) and is well equipped with modern sophisticated equipment for New Formulation Development as well as scale-up of formulations

Quality control

GMP Certified; ISO 9001:2015 Certified; DSIR Recognized; AEO Authorised Economic Operator; 2 Star Export House

Future expansion

- Infrastructure for future expansion and development of other specialty products such as lines for lyophilized, pre-filled syringes, and complex emulsion formulations

Regulatory accreditations

Food and Drugs Authority FDA Ghana; National Agency for Food and Drug Administration and Control NAFDAC; Azərbaycan Respublikası Səhiyyə Nazirliyi; DPML Direction de la Pharmacie, du Médicament et des Laboratoires de Côte d'Ivoire; FDA Food and Drug Administration Philippines; DIGEMID Dirección General de Medicamentos Insumos y Drogas; The Republic of Yemen Ministry of Public Health & Population; Bộ Y Tế Ministry of Health; PMPB Malawi

Note: Regulatory approvals for Yemen, Cambodia, Ivory Coast, Ghana, Nigeria, Malawi, Azerbaijan, and Libya are under renewal process

1 Product registrations designed to achieve growth and margin expansion by realigning BPL's geography focus…

Bharat Parenterals | Innoxel | Varenyam Bio

Product registration pipeline aims to diversify geography mix

Region	First-time filings in new countries to expand presence within the geography	New product filings in select existing countries to deepen presence
LATAM 51% 12.4%	Costa Rica, Ecuador, Panama, Colombia	Nicaragua, Peru, Venezuela
APAC 40% 12.1%	Philippines, Kyrgyzstan, Nepal, Thailand, Malaysia	Cambodia, Myanmar, Uzbekistan, Vietnam
Africa and ME 34% 11.5%	Uganda, Tanzania, Ethiopia, Kenya, Madagascar	Ivory Coast

2023-27 market spending growth (constant USD) 2023-27 market volume growth (standard units)

Source: IQVIA Market Prognosis, Sep 2022; APAC: Asia Pacific, LATAM: Latin America, MOH: Ministry of Health, EUGMP: European Good Manufacturing Practices

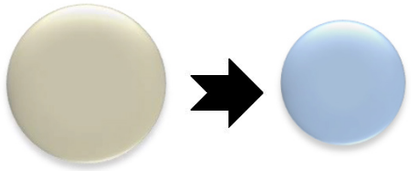
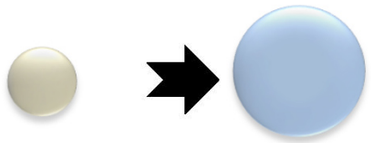
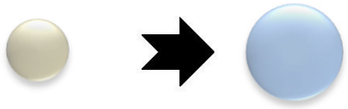
Diversification to achieve growth and margin expansion

Growth objective	• **Enhanced focus** on **APAC** and **LATAM** that have higher volume and value growth vs. Africa
Margin expansion objective	• Across regions, BPL is **prioritizing countries** where **stringent** regulatory and compliance **requirements** have created **high entry barriers**, resulting in **fewer competitors** and **higher margins**

Near-term initiatives to enable diversification

Commissioning two new EU GMP compliant blocks	• Post approval these blocks will enable access to several APAC geographies that accept EU GMP compliant manufacturing facilities
Acquiring Uganda MOH approval for existing blocks	• Inspection and compliance completed. Once approved, will enable access to Uganda
Other	• Plans underway to acquire regulatory approval from several other countries including Ethiopia and Tanzania

...Therapy area focus, and product mix

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

Size of the bubble denotes revenue share. Not to scale

CVS: Cardiovascular, CNS: Central Nervous System

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

Pillars of a regulated market CDMO success story

Operational excellence	Differentiated R&D skill set	Wide clinical experience	Robust regulatory & compliance	Deep commercial networks
Mr. Bharat Desai	Dr. Manish Umrethia	Mr. Manoj Vyas	Mr. Tushar Patel	Mr. Manoj Bharathi
				
30+ years at BPL managing a large **injectable manufacturing** company	CEO of Auxilia Pharma, an **R&D and formulation development** company	CEO of CBCC Global Research, a **Contract Research Organisation** based out of **US** and **India**	CEO of Pharmazone, a provider of **regulatory affairs** and **compliance advisory services**	Director of GeneriQ Pharmaceuticals, a **commercial licensing advisory firm**
Work experience: Bharat Parenterals Limited	**Work experience:** Norbrook, SUN PHARMA, Actavis	**Work experience:** aragen	**Work experience:** veeda clinical research	**Work experience:** aragen
• B.Sc(Chemistry) from SP University	• B.Pharm, M.Pharm (LMCP, Ahmedabad) • Ph.D. (MS University of Baroda) • Post Doctoral (Queens University, Belfast)	• M.Sc. Chemistry (Gujarat University) • Masters Clinical Research (Cranfield University, UK)	• B.Pharm. (LMCP, Ahmedabad) • Masters Clinical Research (Cranfield University, UK)	• B.Tech .Chemical Engineering (Anna University, Chennai) • MBA (IIFT, Delhi)

Supported by a truly state-of-the-art manufacturing infrastructure

Overview

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

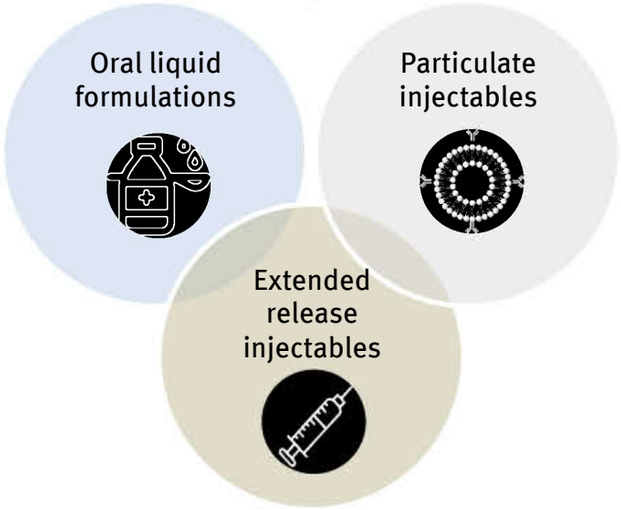
Planned regulatory approvals

FDA U.S. FOOD & DRUG ADMINISTRATION
EUROPEAN UNION GMP

- Acquired an EU MA to trigger inspection from EUGMP
- US Shortage List products being developed to trigger USFDA inspection

Capabilities and capacity

Facility has been designed to support scale up and commercial supply of:



- *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.[2]*
- *Expandable to 6 mn p.a. per line (General and potent lines)*

Differentiated SKID manufacturing

Overview

- A manufacturing SKID is a **system** comprising of a **combination of key process equipment** assembled with **interconnecting inline items** and other specific **instruments to control and monitor** the skid system. SKIDS are usually **product/tech specific** and are always **custom** designed and built.
- Manufacturing of particulate and ER injectables works best when SKIDS are used

Entry barriers for SKID

- Procurement and installation of SKIDS has a **lead time of 9-12 months**
- Investment of **USD 6-8 mn** per SKID
- Requires **expertise** in **sourcing** the right equipment and **designing** the **layout**
- Installing SKIDS in an existing/older facility usually not possible

Innoxel's progress

- Innoxel's facility **built to accommodate** manufacturing SKIDS
- The **components** of the SKIDs planned at Innoxel are **procured** from specialist vendors located in India and Europe
- The **layout is designed** by Manish Umrethia with inputs from the engineering and analytical teams.

EU: European Good Manufacturing Practices, MA: Marketing Authorisation, EU: European Union, sqft: square feet. Note 1: Vial sizes of 10ml considered, Note 2: Bottle sizes of 100 ml considered
ER: Extended release

Identified a set of differentiated technology platforms…

Particulate injectables

- Particulate injectables are usually lipid-based drug vesicles with one of more bilayers enclosing an aqueous compartment.
- They can carry a hydrophilic drug in the aqueous compartment and a hydrophobic drug between the bilayers

Extended release injectables

- 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 solid to oral liquid conversions

- Oral liquid dosage forms of existing solid oral dosage forms which enhance patient convenience and flexibility

Other products with high barriers to entry

- Ready to use injectables (“RTU”)
- Formulations with APIs that are difficult to source
- Products with clinical complexity requiring patient based clinical trials (usually, generic product trials are carried out on healthy patients).

Dual chamber bags

- Dual-chamber bags are two-chamber IV bags made up of polypropylene with a peel-able aluminium foil allowing the storage of unstable drugs which need reconstitution just before the administration to the patient.
- The peel-able seal separates the powder drug and its diluent

Near term pipeline with formulation development completed/underway for several products applying these technologies

Planned future pipeline

IV: Intravenous

…With the ability to formulate solutions for unmet healthcare needs…

Category	Drug characteristics	Impact		
Particulate injectables	• The encapsulated drug is **protected** from rapid **degradation and elimination** by the body	✓		
	• The drug circulates in the body for longer, **allowing for modified drug release** profiles (sustained/controlled)	✓		
	• Usually manufactured with naturally derived starting materials. Offer excellent **biocompatibility** and **safety** and **fewer side effects**		✓	
	• Allow for **targeted delivery** of drug to site of disease and improved bioavailability. This improves therapeutic benefits and causes fewer side effects	✓	✓	
	• Well suited for oncology			
Extended release injectables (“ER”)	• 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	✓	✓	
	• Improved **patient compliance**	✓		
	• Allows for **consistent levels of drugs** in the body - fewer side effects and improved therapeutic benefits	✓	✓	
	• Well suited for CNS disorders, chronic pain, hormonal contraception, and oncology			
Oral solid to liquid conversion products	• Oral liquids are **absorbed more quickly** compared to oral solids	✓		
	• **Convenience** and comfort to pediatric and geriatric populations that struggle with swallowing solid orals			✓
	• Offer **dosing flexibility**. Simple and convenient to change the dosage in case of medicines requiring complex dose titration/adjustment based on body weight	✓	✓	✓
	• Well suited for anti-hypertensives and CNS disorders			

CNS: Central Nervous System

✓ Enhanced effectiveness ✓ Enhanced safety ✓ Enhanced convenience

...And demonstrated track record of commercial success

Existing commercial products based on these technologies address large markets and have witnessed low competition and price erosion

Products	Therapy area	Market landscape			
		Active innovator	Active 505 (b)(2) players	No. of active generic players	Price erosion[1] (FY 21-23)
Key particulate injectable products					
Doxorubicin	Oncology	Baxter	-	6	Moderate price erosion
Amphotericin B	Anti-fungal	astellas	-	2	Stable pricing
Key extended release injectables					
Lanreotide	Hormone	IPSEN	Cipla	-	Negligible price erosion
Aripiprazole	CNS disorders	Otsuka	Alkermes	-	Nominal price increase
Naltroxene	Alcohol dependence		Alkermes	-	Nominal price increase
Risperidone	CNS disorders	Johnson&Johnson	INDIVIOR, teva	-	Moderate price increase
Key oral solid to liquid conversion products					
Zonisamide	Anti-epileptic	-	azurity	-	NA
Amlodipine	CVS	-	azurity, CMP PHARMA	-	Nominal price increase
Enalapril	CVS	-	azurity	3	Moderate price erosion
Perampanel	Anti-convulsant	Eisai	-	-	Nominal price increase
Brivaracetam	Anti-epileptic	ucb	-	-	Nominal price increase
Spironolactone	CVS	-	CMP PHARMA	2	Moderate price increase

Note 1: Price erosion estimates based on market intelligence
CNS: Central Nervous System, CVS: Cardiovascular

Attractive addressable markets

The technologies are used in **chronic** therapies with **large market** sizes and **premium pricing**

Low competitive intensity

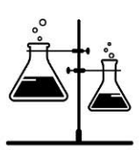
The technological complexity of these products has **deterred competition**. 505 (b)(2) filings have been the most common entry route and there are **very few generics** in the space

Low price erosion

Generic player entries have led to **modest erosion** in pricing. In all other cases, pricing has only improved

Innoxel has strengths across the CDMO continuum to address complexities of the technology platforms

Particulate injectables




	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**
Innoxel's strengths	• Dr. Manish's, **experience in** leading successful particulate injectable generic programs for Sun Pharma • Other key personnel have handled tech transfer and manufacturing of such programs at Sun, DRL etc.	• Mr. Manoj's **experience** with running **large trials** for **complex particulate injectables**.	• Dr. Manish and Tushar's experience with **filing successful ANDAs for particulate 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**

BA/BE: Bioavailability and bioequivalence, ANDA: Abbreviated new drug application, NDA: New drug application, USFDA: United States Food and Drug Association, DRL: Dr Reddy's Laboratories

Innoxel has strengths across the CDMO continuum to address complexities of the technology platforms

Extended release injectables

	Development	Clinical work	ANDA/ NDA filing	Commercial manufacturing
Complexities	• 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**
Innoxel's strengths	• Dr. Manish's **experience - s**uccessfully 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's **experience** with running **large trials** in **oncology, neuropsychiatry** in a **cost** and **time efficient** fashion**.**	• Innoxel's products are **non-infringing** 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**

ANDA: Abbreviated new drug application, NDA: New drug application, USFDA: United States Food and Drug Association, USD: United States Dollar

Innoxel has strengths across the CDMO continuum to address complexities of the technology platforms

Oral solid to oral liquid conversions




	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.
Innoxel'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 on the market.	• Dr. Manish's **experience** with designing and executing bioequivalence/PK studies for 40+ first time oral solid to liquid. • Mr. Manoj'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

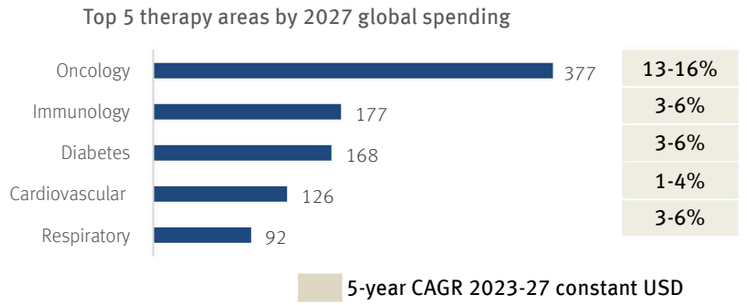
BA/BE: Bioavailability and bioequivalence, PK: Pharmacokinetics, ANDA: Abbreviated new drug application, NDA: New drug application, USFDA: United States Food and Drug Association, EUGMP: European Union Good Manufacturing Practices

Innoxel's pipeline is highly attuned to the market and leverages the team's experience and expertise in complex injectables…

Innoxel's drug	Therapy area	Tech/ complexity	Filing route
INX1014	Confidential	Confidential	ANDA, first wave filer
INX1015	Confidential	Confidential	ANDA, first wave filer
INX1011	Alzheimer's	ER injectable	505 (b)(2)
INX1012	GERD	ER injectable	505 (b)(2)
INX1013	Addiction	ER injectable	505 (b)(2)
INX1017	Oncology	Oral solid to liquid conversion	505 (b)(2)
INX1018	Oncology	Oral solid to liquid conversion	505 (b)(2)
INX1020	Confidential	Confidential	ANDA, potential first filer
INX1023	Thyroid	Lyophilized to RTU	505 (b)(2)
INX1025	Oncology	Lyophilized to RTU	505 (b)(2)
INX2021,22,24	Confidential	Confidential	ANDA

Source: IQVIA Market Prognosis, Sep 2022;
ER: Extended release, RTU: Ready to use injectable

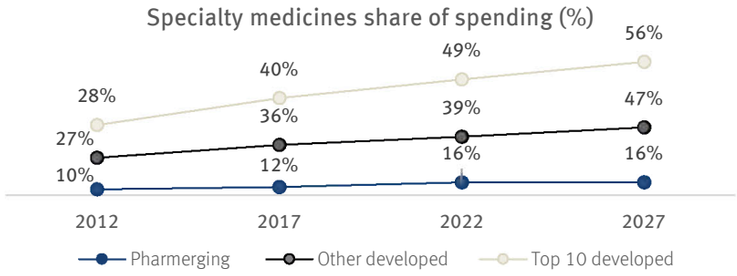
*Large part of pipeline composed of drugs in **Oncology** which is expected to be one of the **largest** and **fastest growing** therapy areas*



*Leveraging the group's commercial manufacturing **experience** in **injectables** and the R&D team's **expertise** in **complex injectables***

30+
years of experience in injectables

*Pipeline with **heavy presence of specialty products (505(b)(2)s)** which is a highly rewarding space in the US markets*



...and provides solutions that meet significant unmet healthcare needs

Drug	Therapeutic area	Unmet need	Innoxel's solution	Tech complexity	Filing type
INX1011	Alzheimer's	Current therapies (oral/transdermal) must be taken daily, and have significant patient adherence issues	Modification of currently approved first line treatment to ER format with an 8-12 week release profile	Extended release injectable	505 (b)(2)
INX1012	Gastroesophageal reflux disease	Current oral therapy must be taken daily and has high discontinuation rates	Modification of currently approved first line treatment to ER injectable format with a 1-2 month release profile	Extended release injectable	505 (b)(2)
INX1013	Addiction	No long-acting solutions available	Modification of currently approved first line treatment to ER format with a 1-2 month release profile	Extended release injectable	505 (b)(2)
INX1016	Confidential	Currently available as large chewable tablets, requiring multiple doses a day.	First ready to drink oral liquid in the market	Oral solid to liquid conversion	505 (b)(2)
INX1017	Oncology	Multiple capsules a day required which cannot be crushed/broken for children/elderly or for patients with swallowing difficulties	First ready to drink pediatric/geriatric friendly oral liquid in the market	Oral solid to liquid conversion	505 (b)(2)
INX1018	Oncology			Oral solid to liquid conversion	505 (b)(2)

ER: Extended release

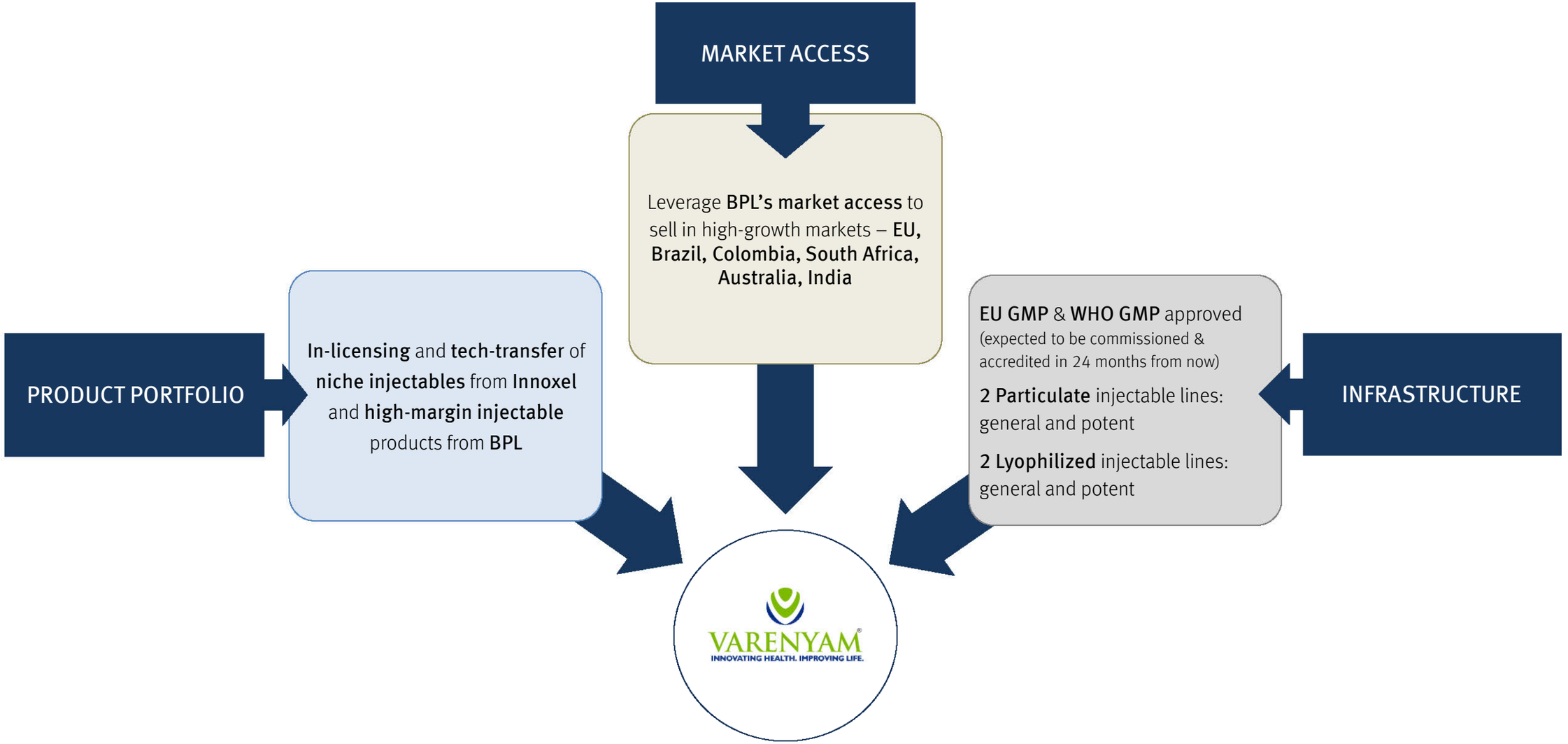
Innoxel's near term pipeline

Innoxel's drug	Therapy area	Tech/ Complexity	Filing route	Formulation development	Pre-clinical studies	Tech transfer	Exhibit batches	Pivotal bio/Clinical trials	Filing (expected date)	Approval (expected date)
INX1014#	Confidential	Confidential	ANDA, first wave filer						Q1 2026	Q3 2027
INX1015	Confidential	Confidential	ANDA, first wave filer						Q1 2027	Q3 2028
INX1011	Alzheimer's	ER injectable	505 (b)(2)							
INX1012#	GERD	ER injectable	505 (b)(2)							
INX1013	Addiction	ER injectable	505 (b)(2)							
INX1017*	Oncology	Oral solid to liquid	505 (b)(2)						Q1 2026	Q3 2027
INX1018*	Oncology	Oral solid to liquid	505 (b)(2)						Q1 2026	Q3 2027
INX1020#	Confidential	Confidential	ANDA, potential first filer						Q2 2025	Q4 2026
INX1023	Thyroid	Lyophilized to RTU	505 (b)(2)						Q2 2025	Q4 2026
INX1025	Oncology	Lyophilized to RTU	505 (b)(2)						Q2 2025	Q4 2026

* Partnered #Term Sheets received

ANDA: Abbreviated New Drug Application, RTU: Ready to use injectable, GERD: Gastroesophageal reflux disease

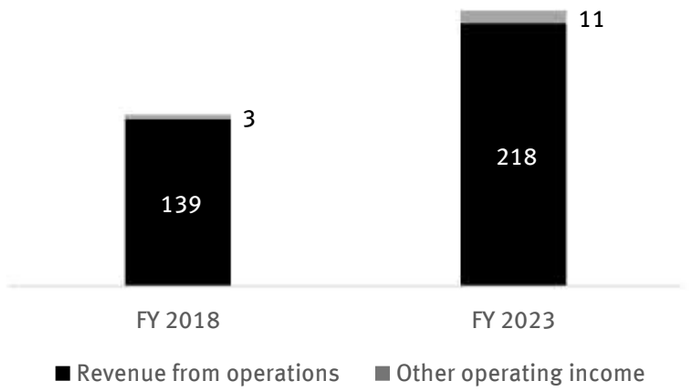
Varenyam Bio leverages Innoxel's complex product portfolio & BPL's market access to further expand the group



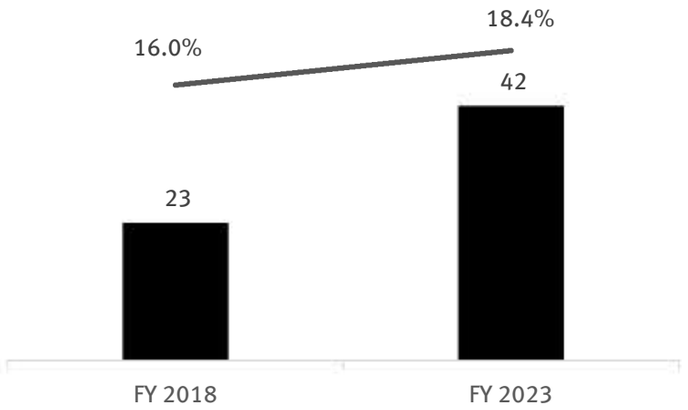
Financial update

Financial metrics | Consolidated numbers

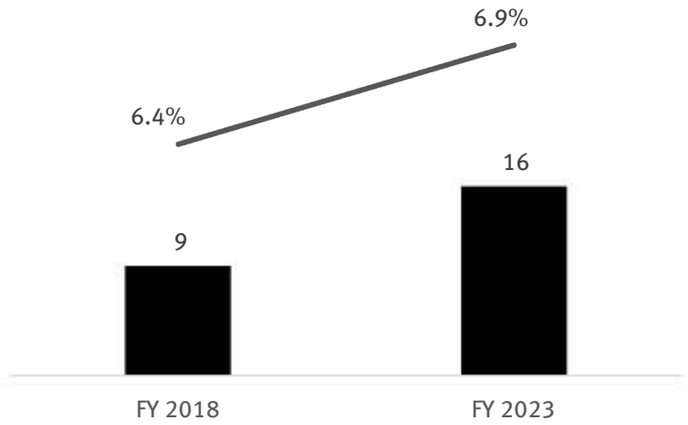
Total operating revenue (INR crore)



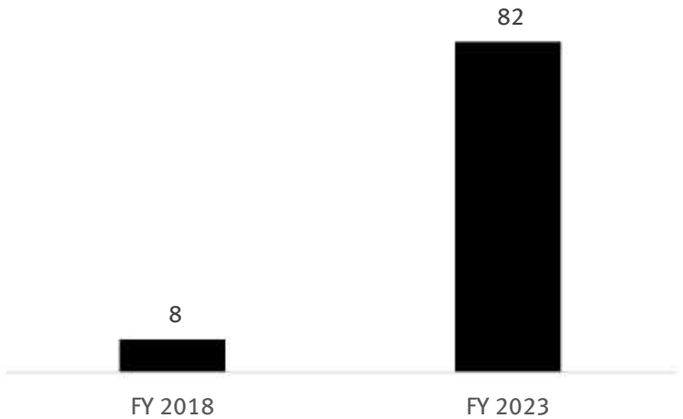
EBITDA (INR crore and as %)



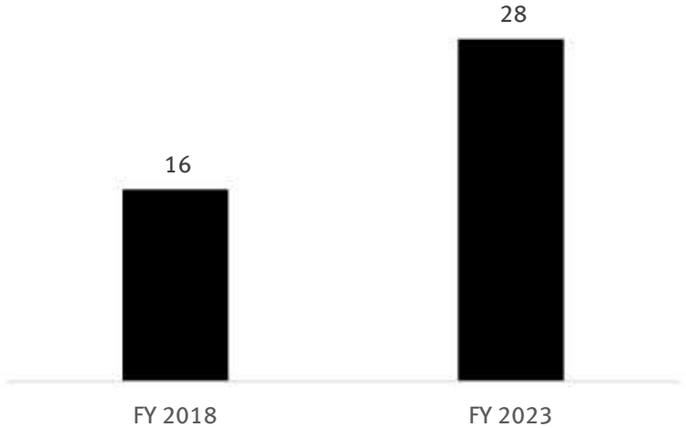
PAT (INR crore and as %)



Capital expenditure (INR crore)



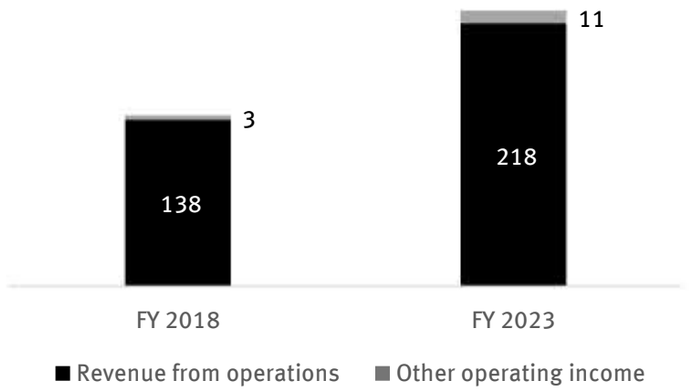
Earnings per share (INR)



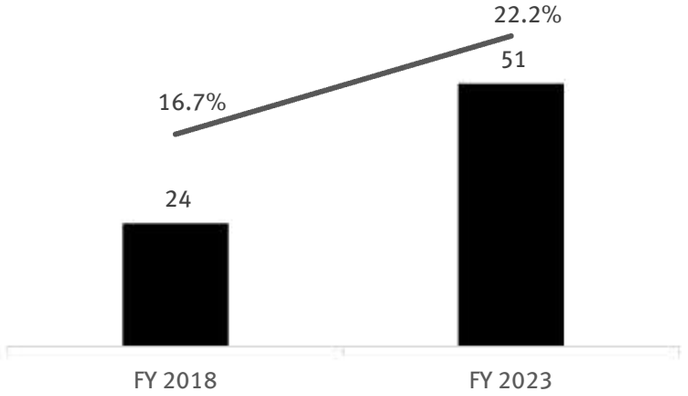
Note: For the calculation of EBITDA and PAT %, we have included other operating revenue in the total revenue due to which there is difference between the numbers presented in this slide and those disclosed in the quarterly results and annual reports.

Financial metrics | Standalone numbers

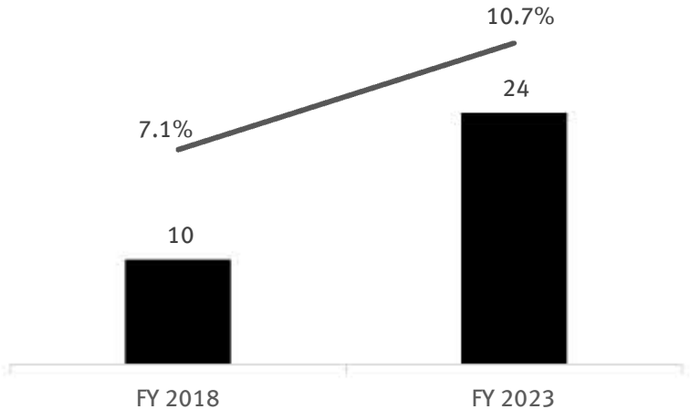
Total operating revenue (INR crore)



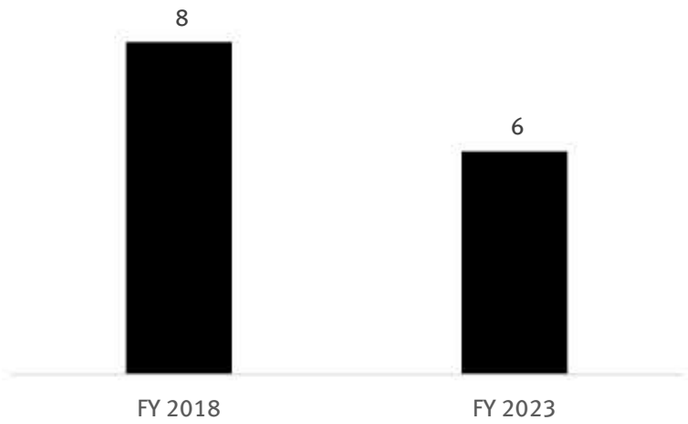
EBITDA (INR crore and as %)



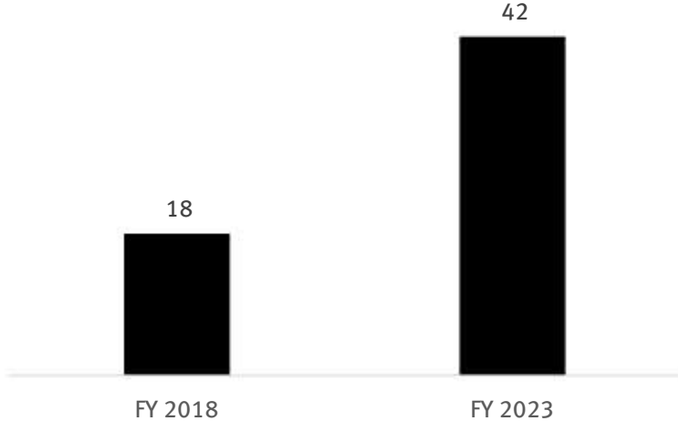
PAT (INR crore and as %)



Capital expenditure (INR crore)



Earnings per share (INR)



Note: For the calculation of EBITDA and PAT %, we have included other operating revenue in the total revenue due to which there is difference between the numbers presented in this slide and those disclosed in the quarterly results and annual reports.

Financial metrics | Consolidated key financials Q3 FY 24

Figures in INR crore

Particulars	Q3 FY 2024	Q3 FY 2023	Change (%)	9M FY 2024	9M FY2023	Change (%)
Revenue from operations	59.8	59.0	+1.4%	189.5	167.0	+13.5%
Other operating revenue	1.2	1.9	-36.8%	5.0	5.8	-13.8%
Total operating revenue	**61.0**	**60.9**	**+0.2%**	**194.5**	**172.8**	**+12.6%**
EBITDA	9.1	8.0	+13.8%	32.3	30.9	+4.5%
EBITDA margin (%)	*15.0%*	*13.2%*		*16.6%*	*17.9%*	
PAT	3.6	2.5	+44.0%	13.1	13.3	-2.2%
PAT (%)	*5.9%*	*4.1%*		*6.7%*	*7.8%*	
EPS (INR)	6.5	4.9	+32.7%	25.6	24.2	+5.8%

Note: For the calculation of EBITDA and PAT %, we have included other operating revenue in the total revenue due to which there is difference between the numbers presented in this slide and those disclosed in the quarterly results and annual reports.

Financial metrics | Standalone key financials Q3 FY 24

Figures in INR crore

Particulars	Q3 FY 2024	Q3 FY 2023	Change (%)	9M FY 2024	9M FY2023	Change (%)
Revenue from operations	58.8	59.0	-0.4%	188.5	167.0	+12.9%
Other operating revenue	1.2	1.9	-36.8%	5.0	5.8	-13.8%
Total operating revenue	**60.0**	**60.9**	**-1.5%**	**193.5**	**172.8**	**+12.0%**
EBITDA	10.4	9.4	+10.6%	38.4	32.5	+18.2%
EBITDA margin (%)	*17.4%*	*15.5%*		*19.9%*	*18.8%*	
PAT	5.1	3.8	+33.1%	19.5	15.0	+29.8%
PAT (%)	*8.5%*	*6.2%*		*10.1%*	*8.7%*	
EPS (INR)	8.7	6.6	+31.1%	33.7	26.1	+29.2%

Note: For the calculation of EBITDA and PAT %, we have included other operating revenue in the total revenue due to which there is difference between the numbers presented in this slide and those disclosed in the quarterly results and annual reports.