

#### **September 26, 2022**

National Stock Exchange of India Limited, Exchange Plaza, Bandra Kurla Complex, Bandra (E), Mumbai-400051, MH.

Symbol: ORCHIDPHAR

BSE Limited Phiroze Jeejeebhoy Towers Dalal Street, Fort, Mumbai-400001

Scrip Code: 524372

#### <u>Subject: Intimation under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.</u>

Dear Sir/Madam,

Pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 we hereby inform you that Meetings of the Investors and Roadshow of Orchid Pharma Limited ("**the Company**") are scheduled to be held as per the details mentioned hereunder:

Commencement Date	End Date	Place	Mode
Monday, Sept. 26, 2022.	Friday, Sept. 30, 2022.	Mumbai	Physical

Copy of the presentation to be presented and discussed during the said events is enclosed herewith for your reference.

Further, the presentation is also available on Company's official website i.e., <u>www.orchidpharma.com</u>

Kindly note that the above schedule may undergo change due to unforeseen exigencies on the part of Investors/Company.

Please take the above information in your record.

Thanking You,

#### For Orchid Pharma Limited

MANISH DHANUKA DHANUKA Digitally signed by MANISH DHANUKA Date: 2022.09.26 14:00:14 +05'30'

Manish Dhanuka Managing Director DIN: 00238798 Encl. as above



# The Road Ahead

September 2022



# Company overview

#### **PIONEER IN CEPHALOSPORIN ANTIBIOTICS**

R&D Focused, Inventor of Enmetazobactam (Ph.-3 Trials done in US & EU)

Acquired by Dhanuka Group through CIRP Process on 1st April 2020

#### 3

#### INTEGRATED CEPHALOSPORIN **API COMPANY SPREAD OVER 60 ACRES**

Worldwide approvals from USFDA, EU, ANVISA, PMDA Widest Portfolio of > 25 products across Oral and Sterile Cephalosporins

#### 6

#### **GLOBAL PRESENCE WITH A WIDE CUSTOMER BASE**

Present in more than 60 Countries More than 200 Customers across US, **Europe and Emerging Markets** 

#### 5

#### **STRONG R&D CAPABILITIES**

Capability to file Para IV applications with USFDA with 8 FTF till date More than 10 process patents and 13 product patents

#### 2

#### **ABOUT DHANUKA GROUP**

~ 2500 Crore diversified group. Interests in Crop Care and Pharma Dhanuka Laboratories is the Pharma arm. >20 years in Antibiotics space

#### **PROFESSIONAL & EXPERIENCED BOARD WITH STRONG MANAGEMENT TEAM**

Over 200 years experience in the board. Over 1000 strong team, with Managers having 15 years experience at Orchid.

#### **FOCUS ON ESG**

7

Highest Standards of Air – Water Emission Control – ZLD – 70% Recycle Community development programs for villages around the company



# History

#### 1992

Orchid was Formed

#### 2005

First USFDA Approval

> FDF Facility Inaugurated by Dr. APJ Abdul Kalam

2008

First ANDA Approval

Partnership with Merck for Drug Discovery

#### 2009

First Para-IV filing for Pip-Taz in collaboration with Apotex

Sells Injectables business to Hospira for \$400mn

#### 2013

Sells NPNC API business to Hospira for \$200mn

Out-license Enmetazobactum to Allecra

#### 2015 - 2017

Goes into CDR and then admitted to IBC 2019

NCLT Approves Dhanuka's plan. Acquisition completed 31st March 2020

#### 2020

Focus on Cost Reduction and Business Turnaround

Slashed costs by 50% > 100Cr

Cleared Phase 3 Trials -Enmetazobactam

#### 2021

Focus on Productivity, Leveraging the Assets

#### 2022

Changing Gears to Overdrive

Awarded PLI for 7-ACA, KSM



# Background and Pedigree

#### **Dhanuka Agritech Ltd.**

- $\rightarrow$  Flagship of the Group founded in 1980.
- → Listed on Stock Exchanges for 35 years with a Market Cap of USD 600mn
- $\rightarrow$  Manufactures a wide range of farm input products
- → The Company has pan India presence with a network of more than 6000 distributors reaching out to more than 10 million farmers
- The Company has technical tie ups with 4 American and 6 Japanese companies

25 September 2022

#### **Dhanuka Laboratories Ltd.**

→ Pharmaceutical arm started in 1998

→ Leader in Cephalosporin Antibiotics in Emerging markets

→ JV with Otsuka - Japan, for manufacturing advanced intermediates

→ 2 API Manufacturing Facilities, both Cephalosporin and NPNC



# Key Rationale for Acquiring Orchid Pharma

Orchid and Dhanuka complement each other to become a formidable force in Antibiotics

#### - Orchid

World Leader in Cephalosporin Antibiotics focused on regulated markets

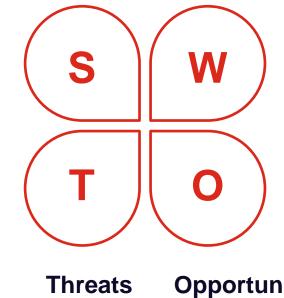
#### **Strengths**

Widest Range

Regulatory Approvals – US / EU / Japan / LATAM

#### Weaknesses

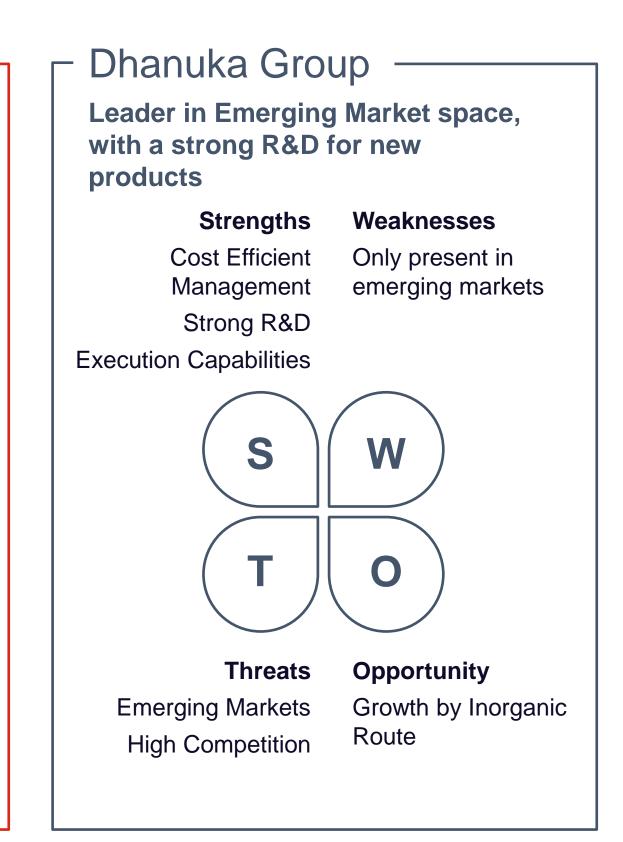
High Cost Structure Lack of focused Management



Financial Stress Competition from Low Cost Chinese Players

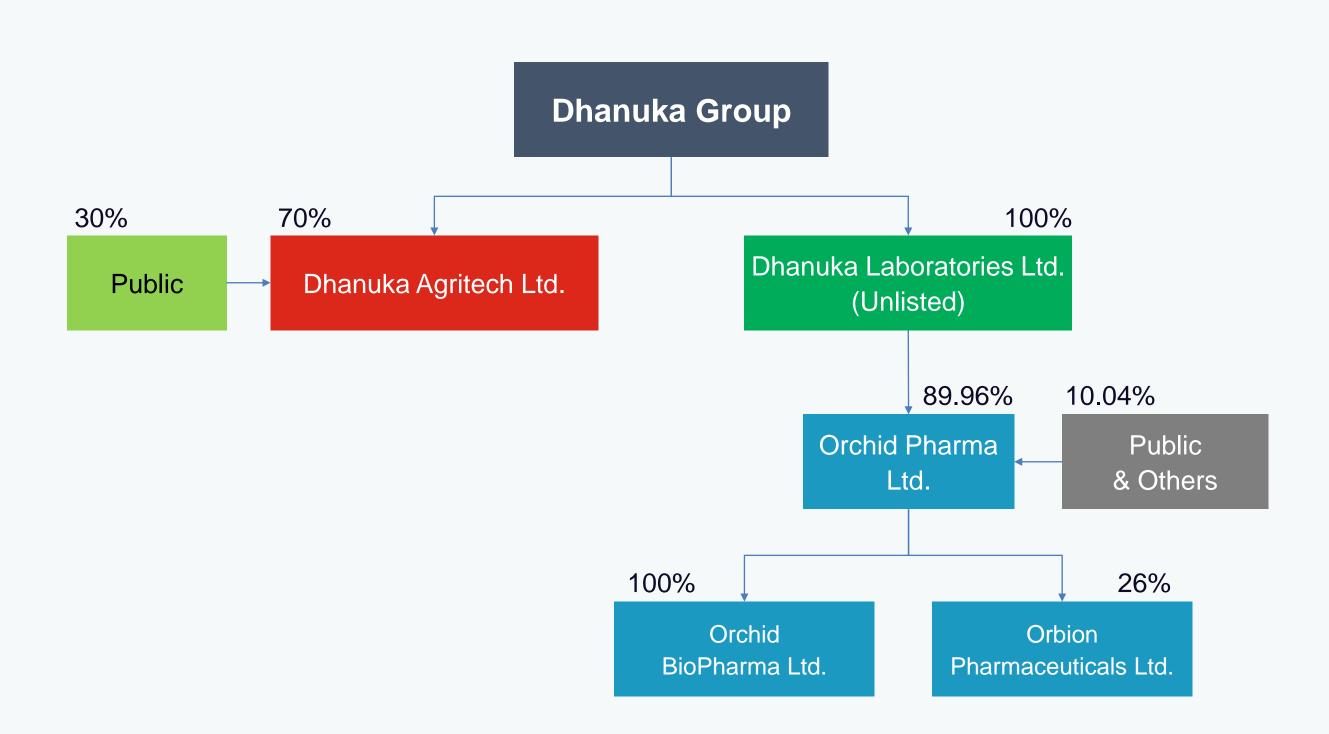
#### **Opportunity** Build on Strengths to

be a World Leader





# Current Corporate Structure



Other insignificant subsidiaries in US / EU are non operative and were linked to non-core business which was sold off to Orbion.



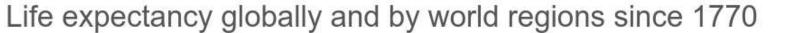
# About Antibiotics



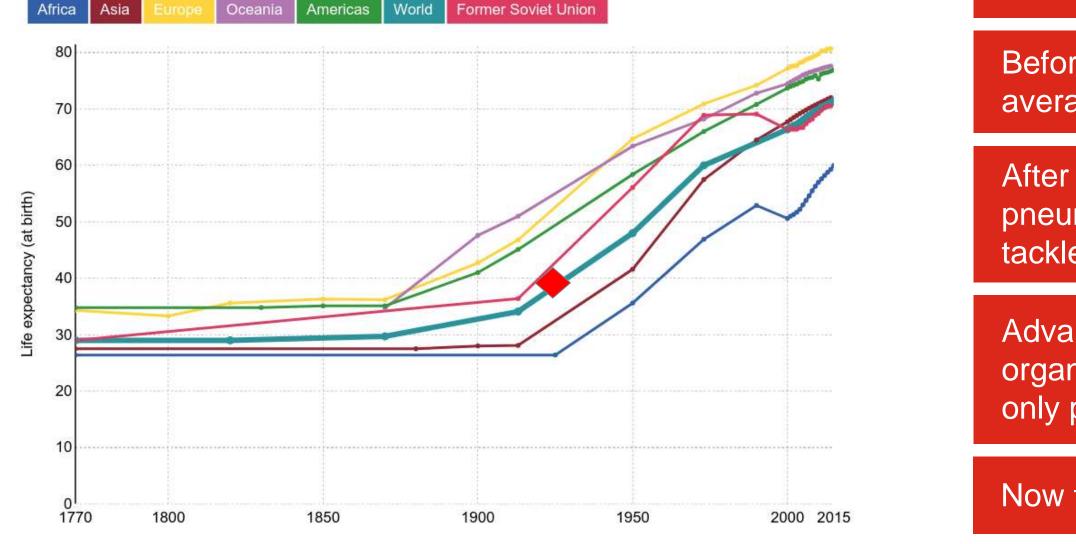




# What are Antibiotics



Our World in Data



Source: Life expectancy - James Riley for data 1990 and earlier; WHO and World Bank for later data (by Max Roser) OurWorldInData.org/life-expectancy/ • CC BY-SA

#### Life Saving Drugs used to fight infections

Before Penicillin by Alexander Fleming, average life expectancy was 40 years

After Antibiotics, basics like child-birth, injuries, pneumonia and stomach infections were tackled which reduced preventable deaths

Advanced procedures like open heart surgery, organ transplant and cancer treatment, were only possible after Antibiotics

Now the life expectancy is 70 years



# Antibiotics Market

#### **Global antibiotics market share**,

by drugs class



Cephalosporin Penicillin Fluoroquinolone  $\succ$ Macrolides Others

#### $\succ$

- Fastest growing at ~ 8% CAGR
- worldwide

- Indian Domestic Size ~ 20,000 Cr

Global Antibiotics Market in 2020 – USD 40 bn.

Cephalosporins is the largest class with 30% share.

> Widest product range with more than 30 products approved

Ceph's have excellent safety profile and wide coverage of bacteria > Newer Class, less resistance to bacteria

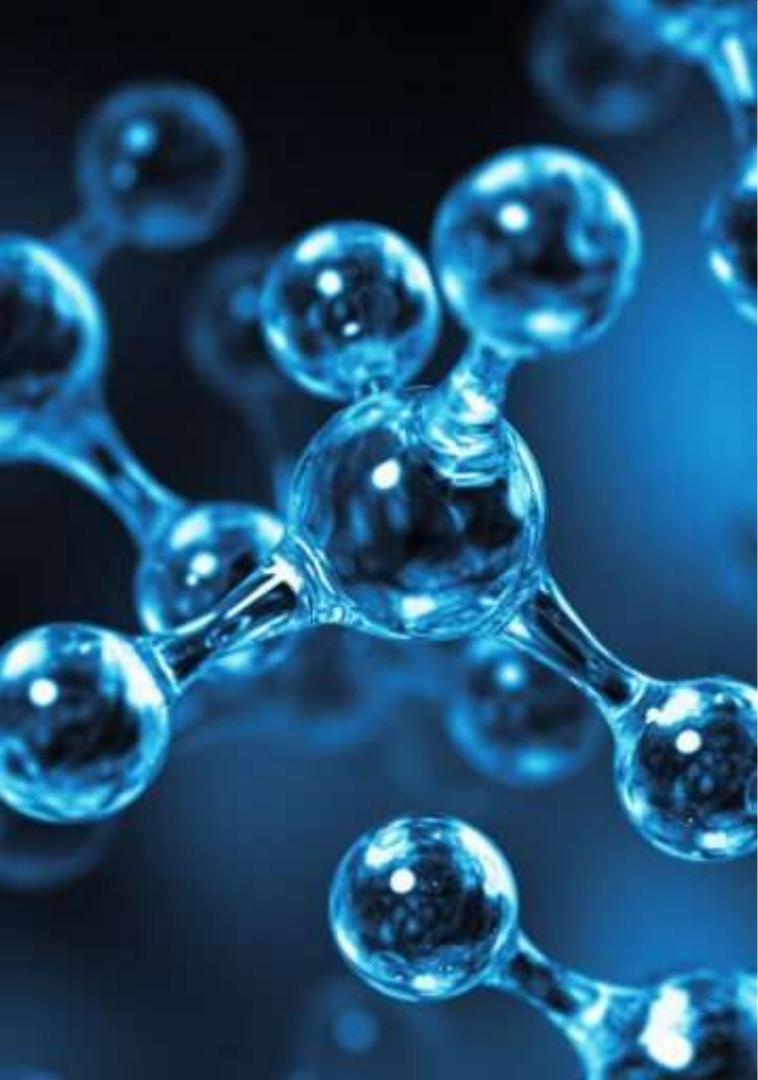
Volumes will see further growth as population increases. Next decade will add ~600mn people in Asia and Africa where access to medicine will improve with rising incomes.

Indian Exports of API and FDF ~ 20,000 Cr



# Why Orchid







# Strong R&D capabilities

Orchid pharma has been focused on R&D, will continue to invest in it



Orchid's expertise encompass the entire spectrum of Pharmaceutical R&D

- 1. Synthesis R&D
- 2. Analytical R&D
- 3. Intellectual Property Management

More than 900 patents filed internationally

8 FTF till date for Orchid

#### All these combined, give us the strength and ability to file First to File Para 4 applications for US and other regulatory markets.

Non – Infringing Process Development

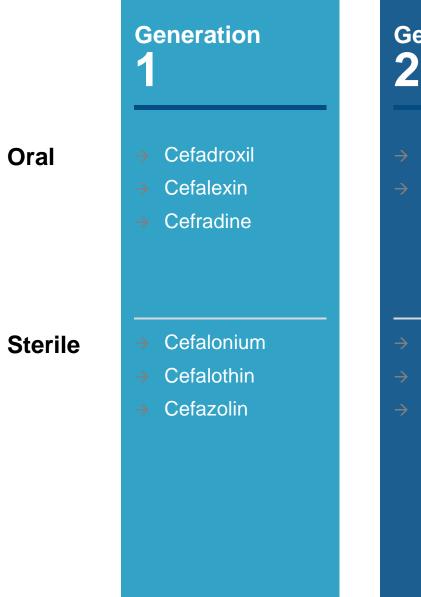
**Impurity Qualification** 

**Impurity Characterization** 

Patent Invalidation Strategy



# Widest range of Cephalosporins



#### Generation

Cefprozil

Cefuroxime

- Cefoxitin
- Ceforanide
- Cefotiam

#### Generation 3

- Cefdinir
- Cefditoren
- Cefixime
- Cefpodoxime
- Ceftibuten
- Cefotaxime
- Ceftiofur
- Ceftizoxime
- Ceftriaxone
- Cefoperazone
- Ceftazidime
- Cefovecin
- Cefcapene

#### Generation 4

- → Cefepime
- Cefpirome
- Cefquinome
- Cefiderocol

Ready to launch

Under development

# Generation Generation 5 Ceftaroline Ceftobiprole Ceftolozane

- 6
- Cefepime + Enmetazobactam
- Ceftazidime + Avibactam



# Leading - Integrated Cephalosporin API company









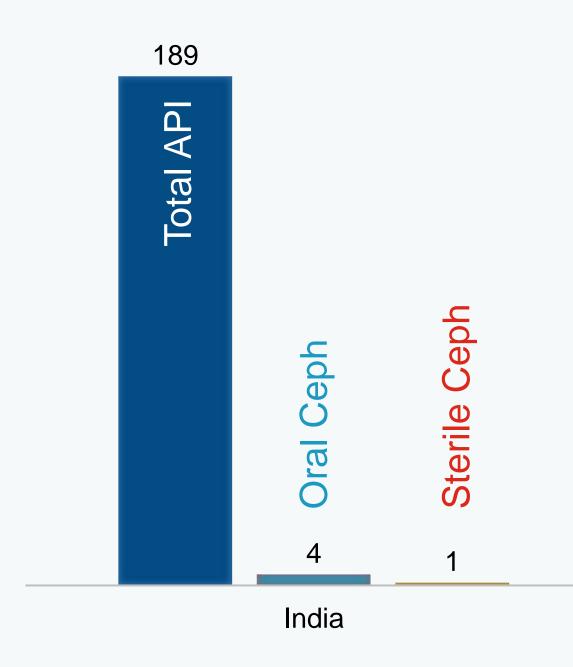




- Vertically integrated with credentials in research, development, manufacturing and marketing
- Integrated facilities from Intermediates to API spread across 60 acre, approved worldwide
- Presence across the antibiotic domains spread across oral and sterile categories of more than 30 products
- □ Multiple Blocks
  - □ Sterile 3 Crystalline and 1 Lyophilized
  - Oral 7 Blocks
  - Intermediates 5 Blocks
- Footprint across 60 countries through direct presence, alliances and partnerships



### **Unique Fact** about Orchid's **Facilities**



#### **USFDA APPROVED API SITES**

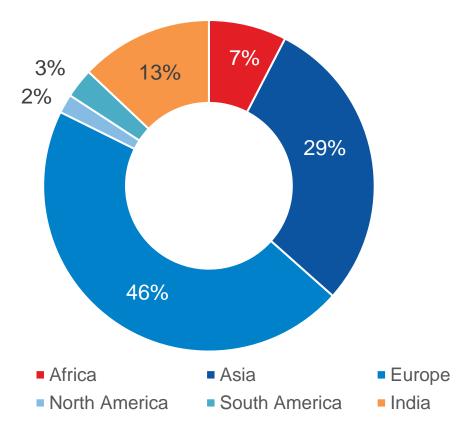


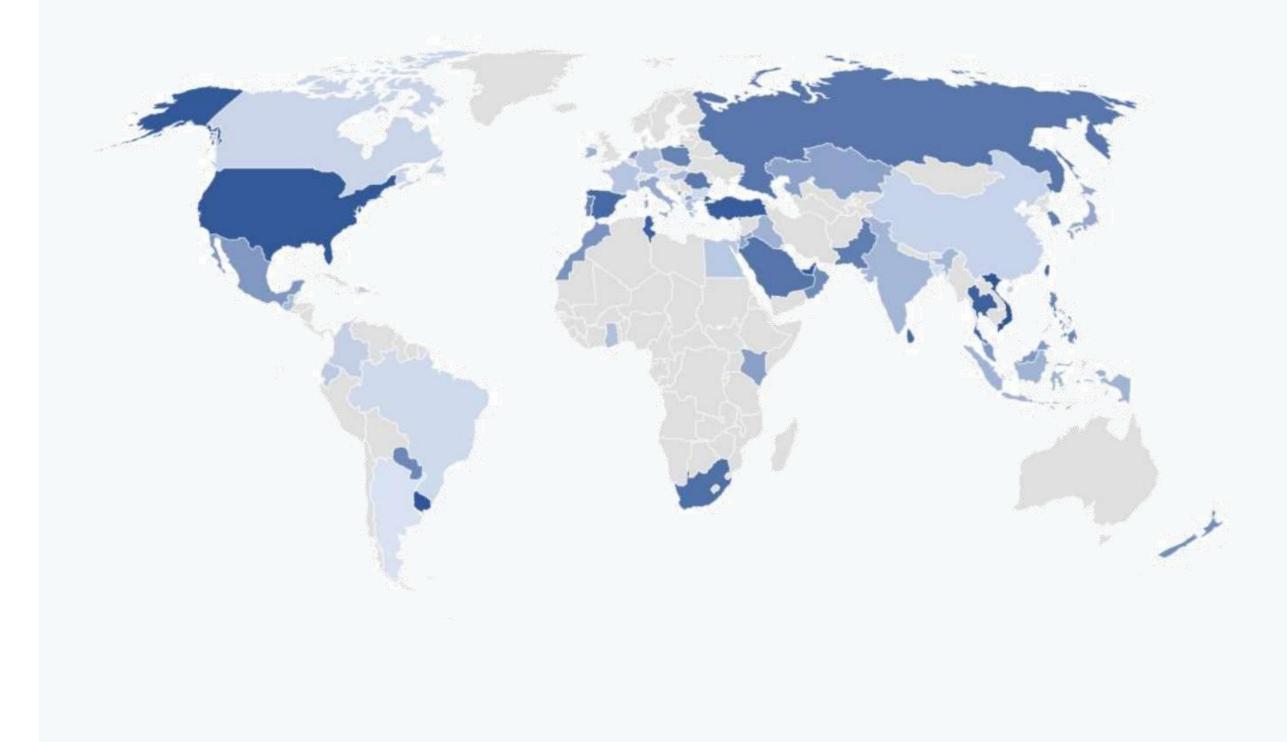
China



### Global Presence with a Wide Customer Base

Revenue Breakup by Geography (FY-22)







### Experienced Board & Management Team



#### Mr. Ram Gopal Agarwal

Chairman and Non-Executive Director

Founder Chairman of Dhanuka Group with over 5 decades of leadership experience Chairman of FICCI Crop Protection Committee



#### Dr. Dharam Vir

Independent Director

Ph.D. in synthetic chemistry with more than 3 decades of R&D experience at various Pharma majors



#### Mr. Manish Dhanuka Managing Director

Visionary Leader at the helm of affairs of Pharma Division.

An IIT'ian with 25+ years in Pharma Industry Director at JV with Otsuk, Japan



Independent Director

Graduate of ISB and worked in Venture Capital field

Runs a large fashion accessory company



#### CA Sunil Kumar Gupta CFO

CA, with 36 years of experience in varied industries as financial

controller



#### Dr. S Srinivasan

Head CTD & IPM

Ph.D. in Synthetic Organic Chemistry. 26+ years of experience in new product development for small molecule APIs, Process development & optimization.





#### Mr. Arun Dhanuka

Non-Executive Director

Director at DLL, DAL and Orchid with over 4 decades of experience In-charge of commercial matters of the Pharma Division



#### Mr. Mridul Dhanuka

Whole-Time Director

Chemical Engineer & MBA; Associated with Dhanuka Group Ltd. since 2005.

Operations Head at Dhanuka Agritech, now moved to Orchid.



#### Ms. Tanu Singla

Independent Director

Qualified Company Secretary, L.L.B and She has expertise in Business Management, Finance, Accounts, Audit, real estate



#### CA Manoj Goyal

Independent Director

Practicing CA and an auditor of banks and other large businesses.

He was a Statutory Auditor of different Banks, Insurance Companies and public sector undertaking

#### Dr. RJ Sarangdhar

Site Head of Ceph API

3 decades of experience in process development, technology transfer and more than 10 patents to his credit



#### Mr. D Chellapandi

#### SGM-Engineering

35+ years of experience in operation, maintenance of engineering functions, energy conversion, solvent recovery and environment management



### **Competitive Advantage**





### Dhanuka -----





#### Complexity

- Chemistry of Cephalosporins
- → Sterile Manufacturing

#### **High Entry Barrier**

- → Cross Contamination Barrier
- → High Capital Costs



#### **Cost Leadership**

- → Lowest Cost of Management
- $\rightarrow$  Low Cost of Operations



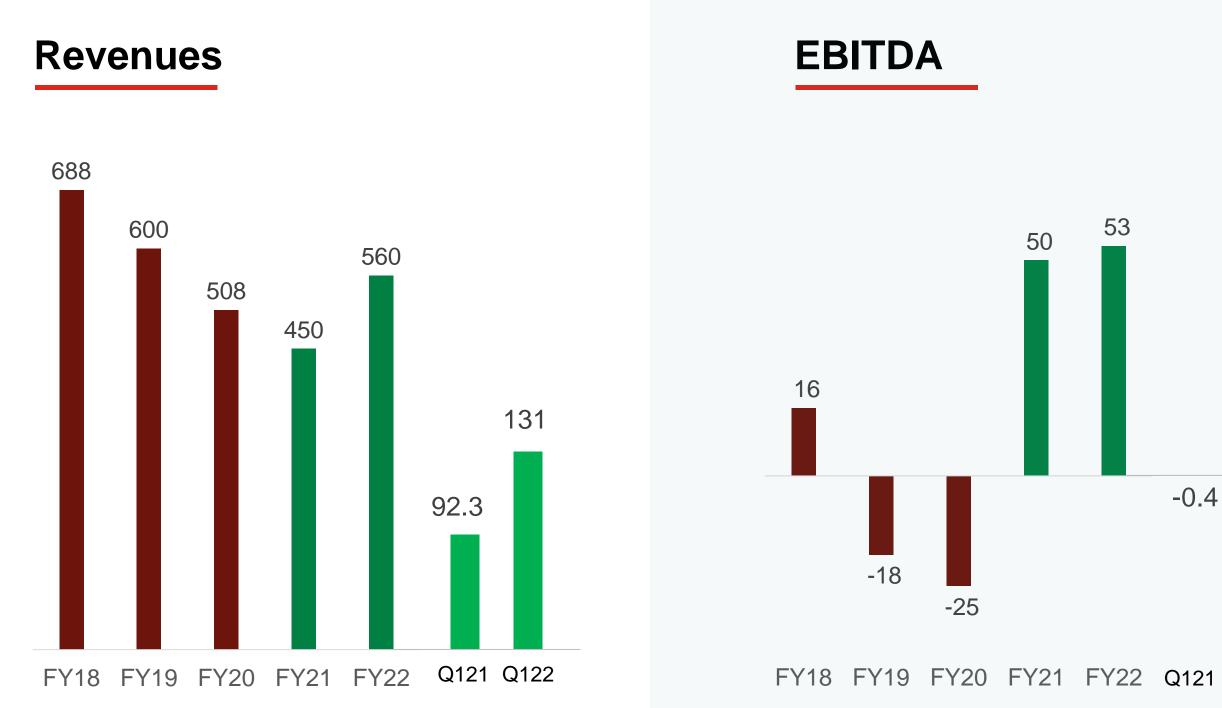
# Progress So far





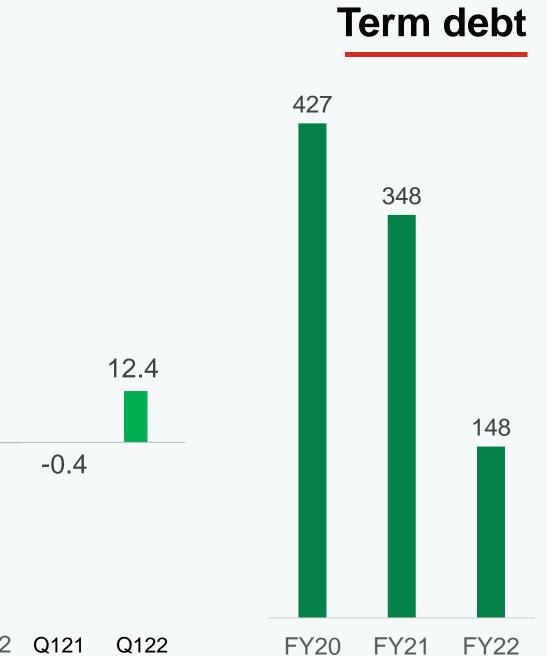


### **Progress of Turnaround**











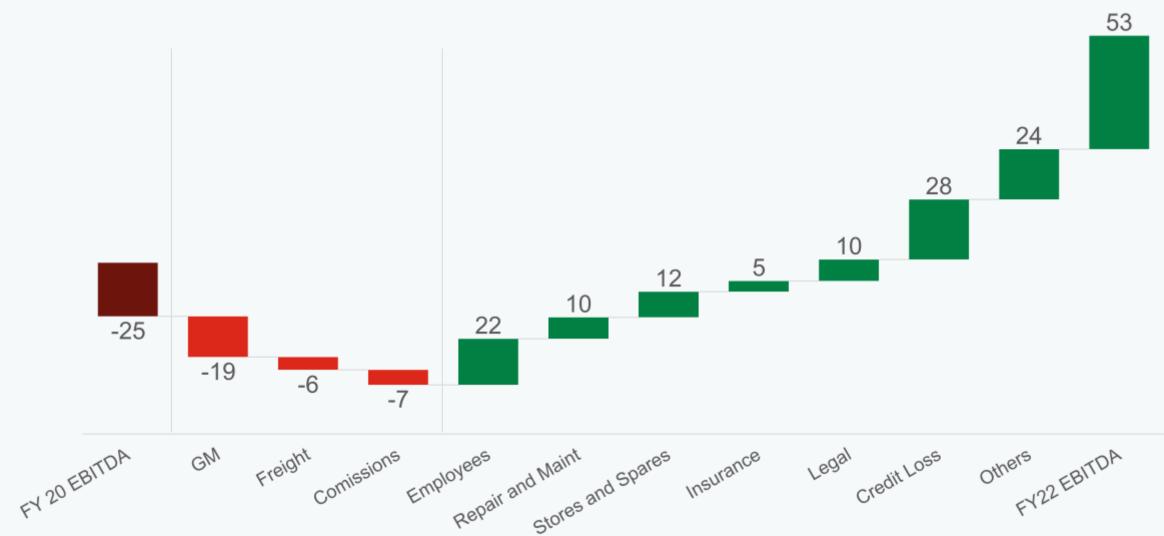
### Cost control measures have increased Efficiency and Profitability

#### Headwinds

- $\rightarrow$  Covid struggle
- → Poor demand from Europe
- $\rightarrow$  Energy
  - Coal pricing more than doubled
  - Electricity costs increased

- → 36% Increase in Sales Qty
- $\rightarrow$  12% Increase in Expenses

#### EBITDA Build up (Cr)



\*groupings not as per FS



# Future Strategy





# Growth Drivers



#### Scale

#### 7 ACA and Downstream Products

#### **New Products**

#### New Chemical Entity – Enmetazobactam



# Scale Growth Driver



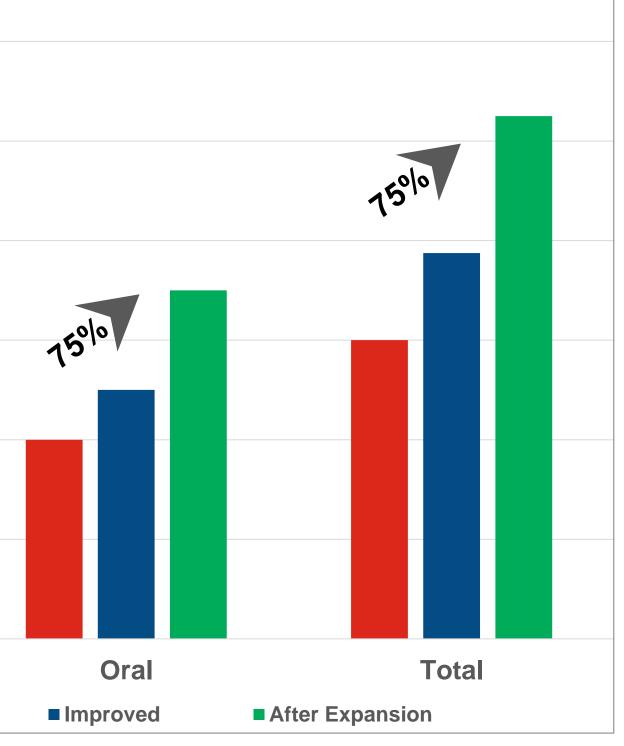


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# Scale – Capacity Addition

1200				
1000				
800				
600				
400	150	0	_	
200				
0				
	Sterile			
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1			-	





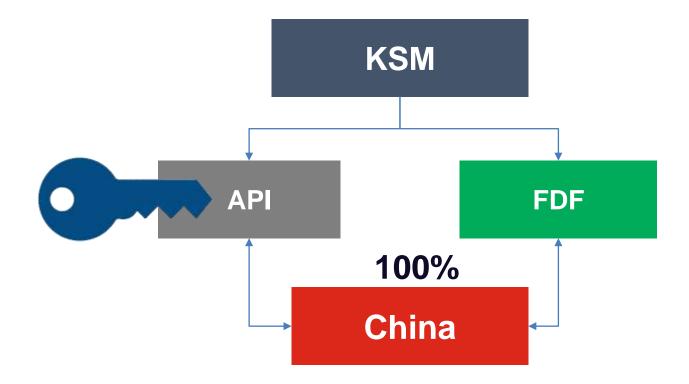
# 7ACA and Downstream Products Growth Driver





### Pharmaceutical Business





#### **Government PLI Scheme**

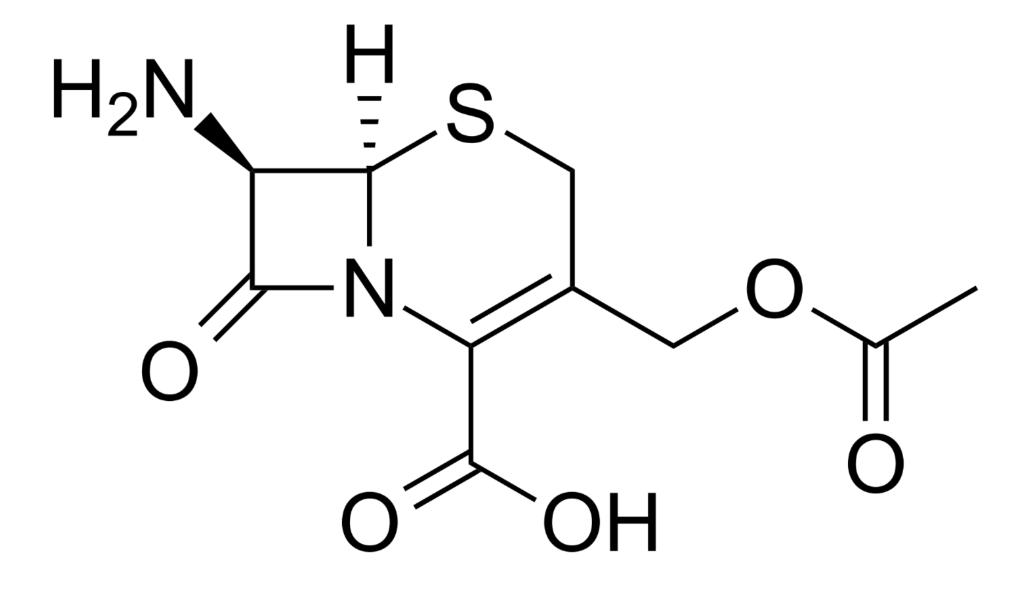






# 7ACA

# 7 Amino Cephalosporanic Acid





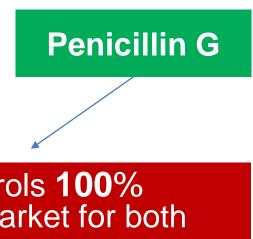
# Importance of 7ACA

- $\rightarrow$  7ACA is not just another pharma intermediate
- $\rightarrow$  All Cephalosporin Antibiotics are manufactured from 2 Key Starting Materials which are produced through fermentation
- $\rightarrow$  Without Antibiotics, infection fighting is impossible



7ACA

China controls **100%** of the world market for both





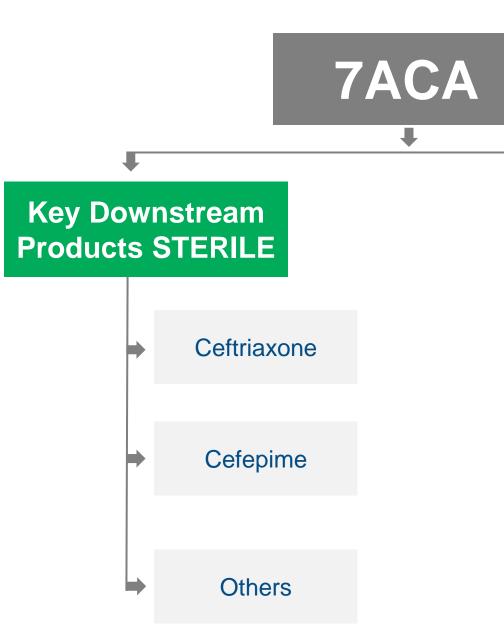
This is a matter of health security of our nation

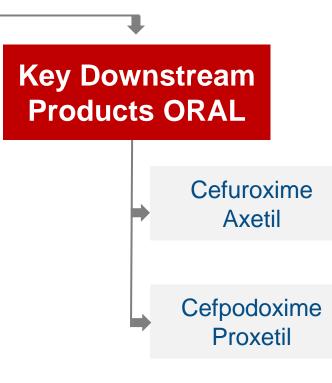


# Uses of 7ACA

 → ~ 30 Cephalosporin APIs approved worldwide
 → More than 20 have

7ACA as the KSM







# Size of 7ACA Market

(including downstream products)

World Market

- → ~ 10000MT ~ \$600mn growing at 5% CAGR
  - Adding 500MT demand per year.
- → China controls 100% world market



#### India Market

- $\rightarrow$  India Market Size ~ 4000MT of 7ACA
  - Key Downstream Products –
     Sterile
    - Ceftriaxone 6000MTPA world market,
    - 2000MTPA Imports into India
  - Key Downstream Products Oral
    - Cefuroxime Axetil and Cefpodoxime Proxetil – 1500MTPA

#### Orchid

#### ightarrow 1000MTPA per annum





### PLI – A Step towards



# **AATMA-NIRBHAR**

- $\rightarrow$  ~ Price of 7ACA = \$63
  - PLI from GOI @ 20% •

#### Location – Jammu

- → 18% GST Refund

#### **Current Status**

- → Land under Acquisition Stage in Jammu
- $\rightarrow$  Pilot Plant setup at Orchid, Chennai started
- $\rightarrow$  Commercial Production Jan 2025

#### $\rightarrow$ Orchid has received 1000MTPA approval from Government of India in its WoS – Orchid BioPharma Ltd. (OBPL)

→ Benefits under New Central Sector Scheme for Industrial **Development of Union Territory of Jammu & Kashmir** 



# **7ACA Downstream Products**

80% will be used by Orchid-in-house

- $\rightarrow$  55% shall be used to make **1000MT** of **downstream** products at an average price of \$85
- $\rightarrow$  25% is Orchid's current self Imports

# 20% will be sold in the open market





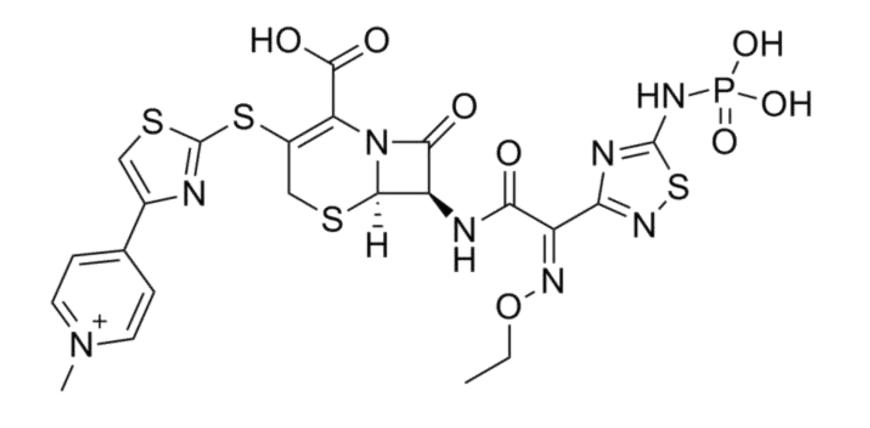
# New PRODUCTS Growth Driver







### Ceftaroline



#### ORIGINATOR $\rightarrow$

- Forest Labs (Allergan)
- **MARKET SIZE**  $\rightarrow$ 
  - US USD160mn
  - ~ INR 1250 Crore
- $\rightarrow$ and price will reduce

**Orchid Target Dates US Market** 

- $\rightarrow$  DMF Filing June 2023
- $\rightarrow$  ANDA Filing Jan 2024

#### **Other Markets**

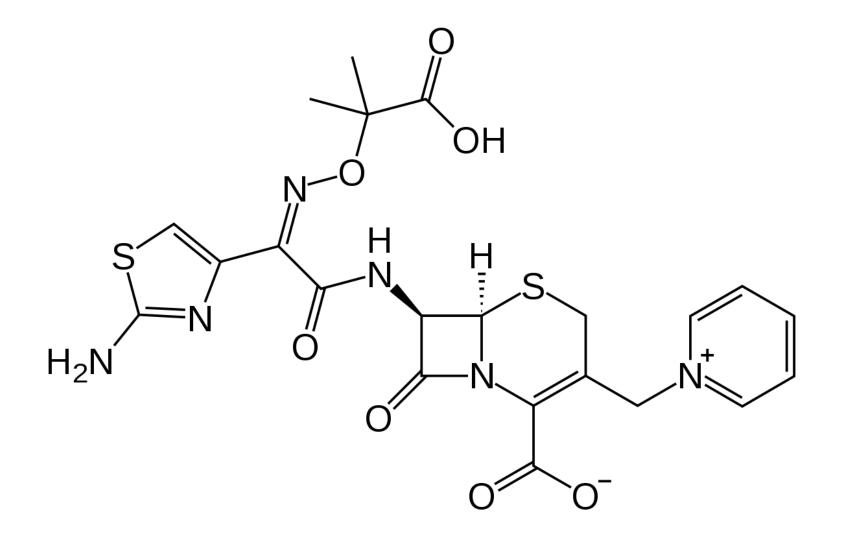
After Patent Expiry in 2023, volume will multiply

 $\rightarrow$  We estimate a net market size multiplication by 2x after Genericization ~ 2500 Cr

 $\rightarrow$  Product Available in Jan 2023



### **Ceftazidime/ Avibactam**



#### ORIGINATOR $\rightarrow$

- Allergan /
- MARKET SIZ  $\rightarrow$ 
  - USD 450
  - ~ INR 360

#### PATENT STA $\rightarrow$

- US Nove
- Emerging
- After Patent E  $\rightarrow$
- We estimate a  $\rightarrow$ Genericization

#### **Orchid Target Dates**

#### **US Market**

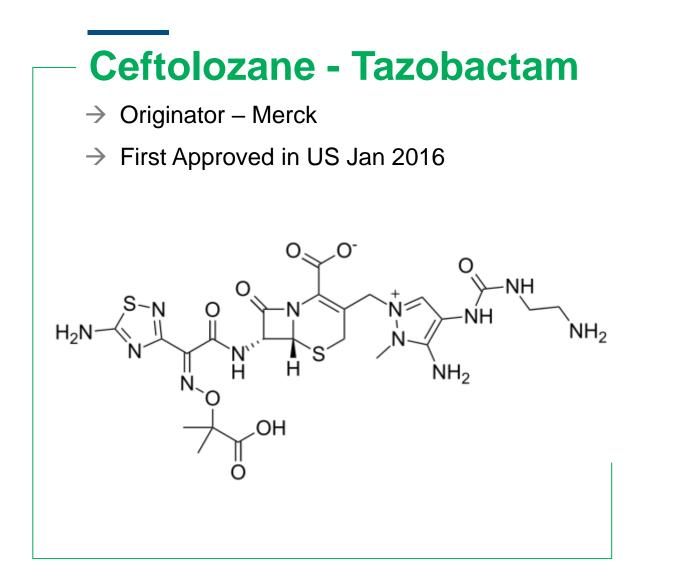
 $\rightarrow$  FTF Para IV - ANDA Filing – Feb 2024

#### **Emerging Markets** $\rightarrow$ Product Available in Jan 2023

2
Pfizer
E
Mn
0 Crore
TUS
ember 2026
Markets – January 2023
Expiry, volume will multiply, and price will reduce
a net market size multiplication by 1.5x after n ~ 5400 Cr

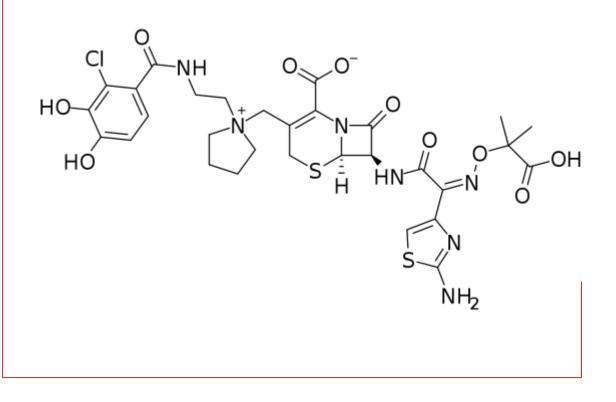


### **Future Products** Pipeline





- → Originator Shionogi
- $\rightarrow$  First Approved in US Nov 2019





# NCE Enmetazobactam Growth Driver





### Antibiotic Resistance – The challenge





Poor infection control in hospitals and clinics

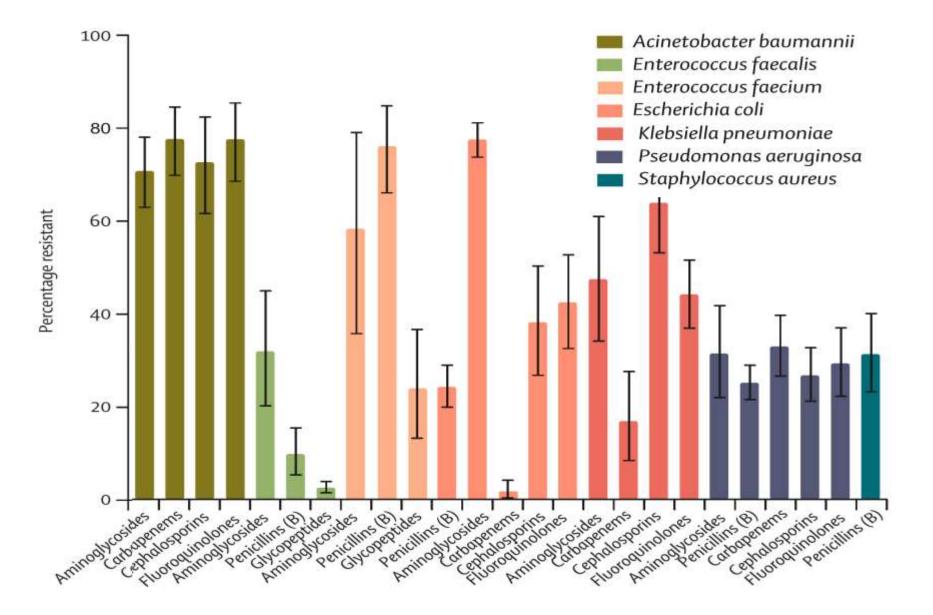




Unnecessary antibiotics used in Animal Husbandry



Patients not taking antibiotics as prescribed





### Importance of Enmetazobactam



- make it effective again
- $\rightarrow$ Antibiotic in the world today
- Phase 3 Clinical Trials were cleared in  $\rightarrow$ December 2020
- $\rightarrow$ BLI combination just like Cefepime – Enmetazobactam and std of care for UTI)
- Against 59% Efficacy of Pip-Taz,  $\rightarrow$ Enmetazobactam is 79% effective

Enmetazobactam – a Beta Lactamase Inhibitor (BLI), lowers the resistance of the Antibiotic to

Best example – Augmentin of GSK, a 50-yearold drug. Combined with BLI, is largest selling

Compared with Piperacillin – Tazobactam (BL-



## World Market Estimation Indicators

PIP-TAZ market
~ \$1bn
at Patent Expiry

AVYCAZ market of ~\$450mn

CEFTRIAXONE 6000MT worldwide market

#### Looking at its Potential,

- → December 2020, out-licensed to Shanghai Haini Pharmaceuticals for Greater China at a value of USD 78 Mn plus royalties
- → Jan2022, out-licensed to Advanz Pharma for Europe, for milestone payments, in addition to double-digit royalties

- → Estimated annual global sales of USD 200 Mn –300 Mn pa (10Y Avg)
- → Orchid entitled to Royalty from Allecra
   ~ USD 16 Mn USD 25 Mn pa
- Orchid has rights to develop and commercialize the molecule in India



### Enmetazobactam -Domestic

**Domestic Injectable Antibiotic Size 7000 Crore** 

#### **Largest Products**

ыр-тад 800 ~ 1000 Cr

20% Better Efficacy

### CEFTRIAXONE 1200 ~ 1500 Cr

Bacteria are already resistant

## MEROPENEM ~ 1000 Cr

This is a Carbapenem. Last Resort Antibiotic. Should be saved for more serious diseases.

#### **Orchid Target Dates**

- → Filing of Application Jan 2023
- → Clinical Trial Complete Jan 2024
- $\rightarrow$  Approval of Drug and Launch April 2024



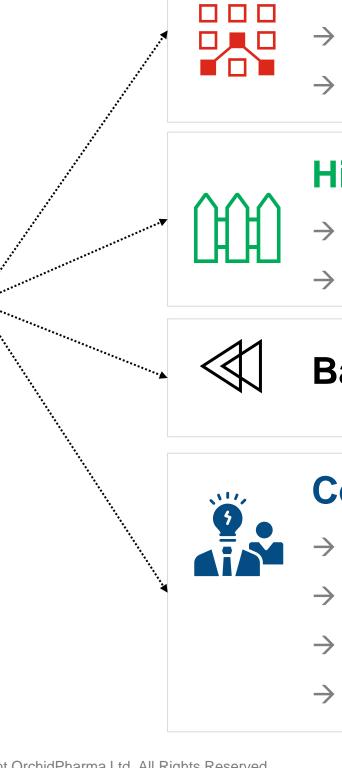
# Future Direction





## Building Competitive Advantage





### Complexity

- → Chemistry of Cephalosporins
- → Sterile Manufacturing

### **High Entry Barrier**

- → Cross Contamination Barrier
- → High Capital Costs

#### **Backward Integrated**

#### **Cost Leadership**

- → Low Cost of Management
- → Low Cost of Operations
- $\rightarrow$  Scale
- $\rightarrow$  Low Dependence on China



# New Possibilities

01 Building on the Backward Integration Strength

02 Start work on Forward Integration

25 September 2022





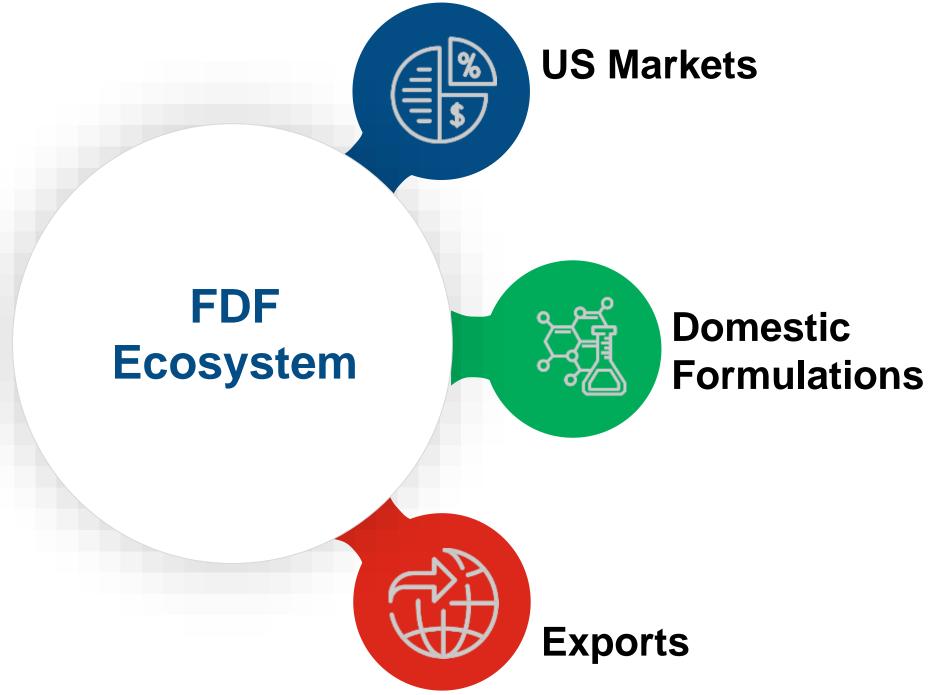
### Pharmaceutical Value Chain

FDF

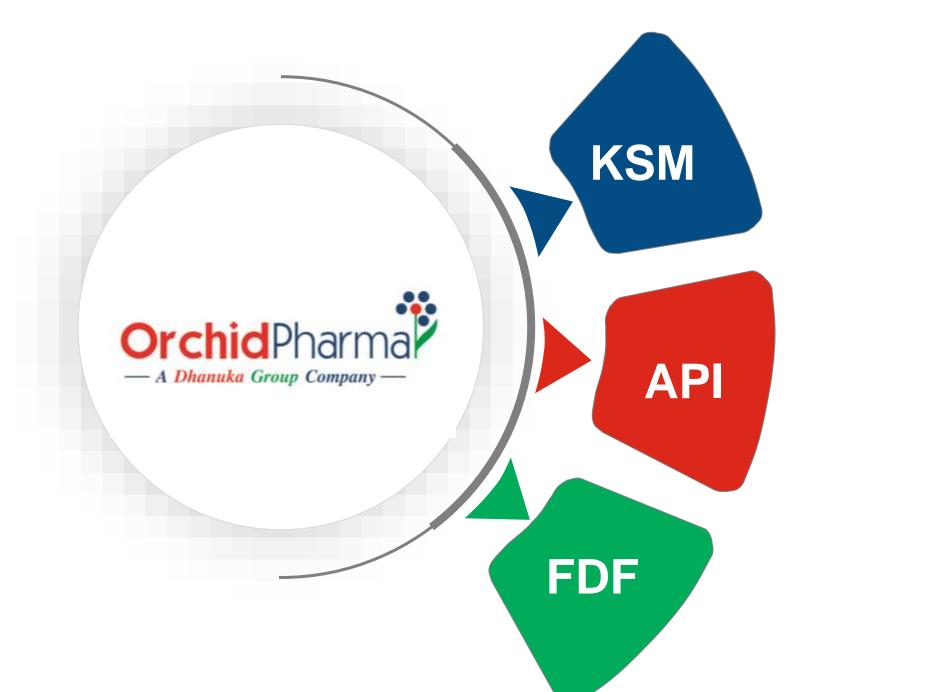




## FDF Ecosystem







# Thank You!



