

# Catalent<sup>®</sup>

INHALATION

Evolving technologies shaping  
new research needs for future  
pulmonary and nasal generics

FDA/GDUFA WORKSHOP

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VICE PRESIDENT SPECIALTY DRUG DELIVERY

CATALENT PHARMA SOLUTIONS



DEVELOPMENT



DELIVERY



SUPPLY

more products. better treatments. reliably supplied.™

# Disclaimer

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The views and opinions expressed in this presentation are solely my own and do not necessarily reflect the official policy or position of Catalent

# Agenda

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- Evolving Landscape of Nasal and Pulmonary Pipeline 01
- New delivery platforms in Dry Powder for Inhalation 02
- Advances in device systems driving new therapies 03
- Evolution to multi-therapeutic modalities 04
- The Future new generics – what research is needed long term 05

# Evolving Landscape of Orally Inhaled & Nasal Drug Products

**Pipeline renovation  
in both pulmonary  
and nasal delivery**



**~460**  
Molecules in  
Development



**+8%**  
Growth vs.  
Prior Year



**~50%**  
In Pre-  
Clinical

**Innovation driven  
by biologics and  
new modalities**



**~40%**  
Biologics in  
Pre-Clinical



**~50-60%**  
New  
Modalities  
in Pre-Clinical



**40%**  
Nasals  
are Vaccines

**New therapeutic  
classes and targets  
require different  
formulations**



**~60-70%**  
Non-Respiratory  
Therapeutic  
Targets



**~55%**  
Anti-Infective  
Therapies

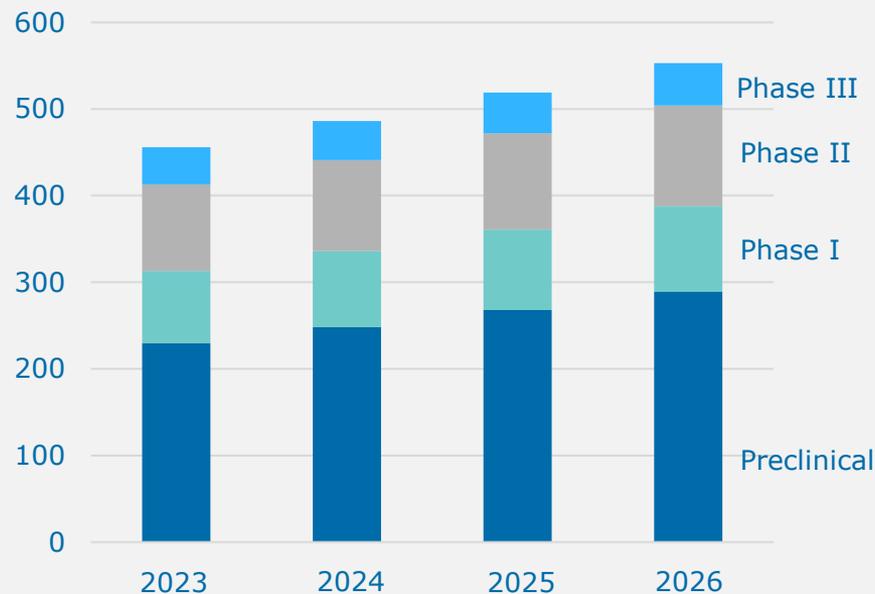


**~20%**  
CNS  
Therapies

# Inhaled & Nasal Development Pipeline and delivery platform

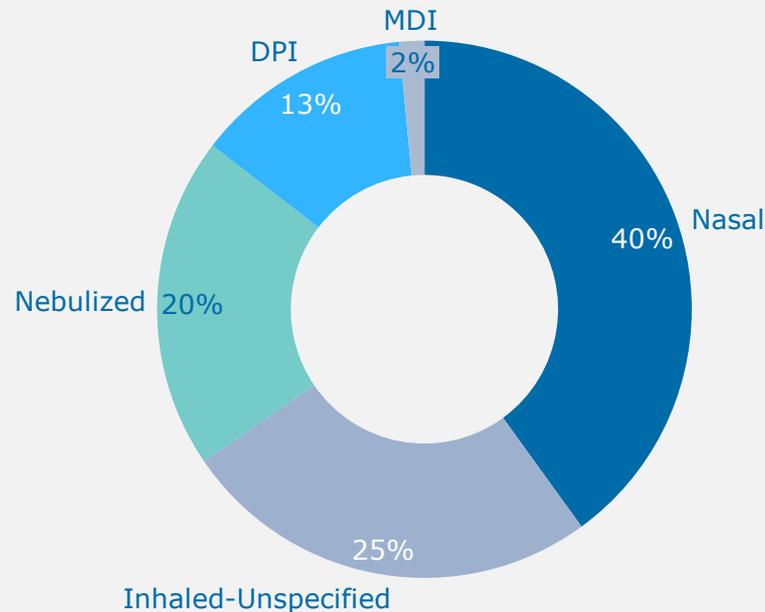
## Inhalation & Nasal Molecule Pipeline by Phase

Number of Molecules



## Inhalation Pipeline by Modality

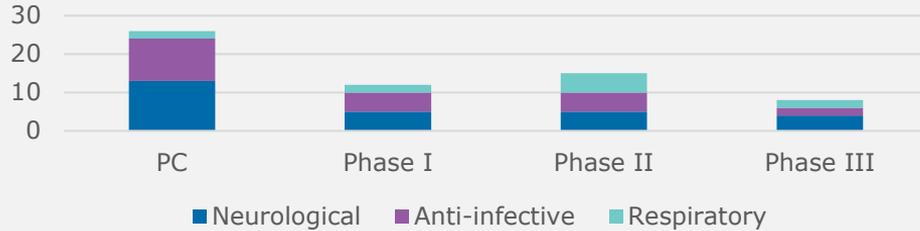
~ 460 Pipeline Molecules



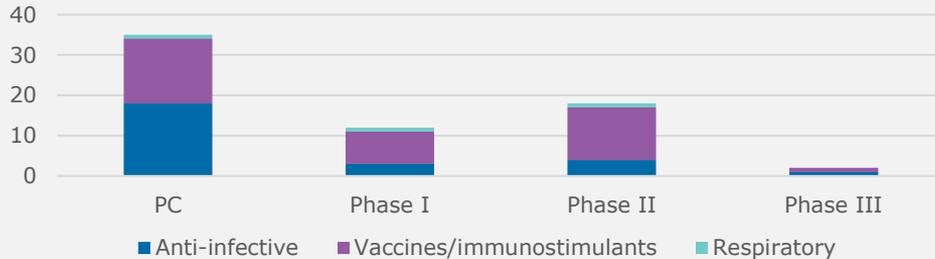
Source: PharmaProjects, Internal Analysis

# Therapies beyond respiratory conditions

## Small Molecule Nasal Pipeline by Phase



## Large Molecule Nasal Pipeline by Phase

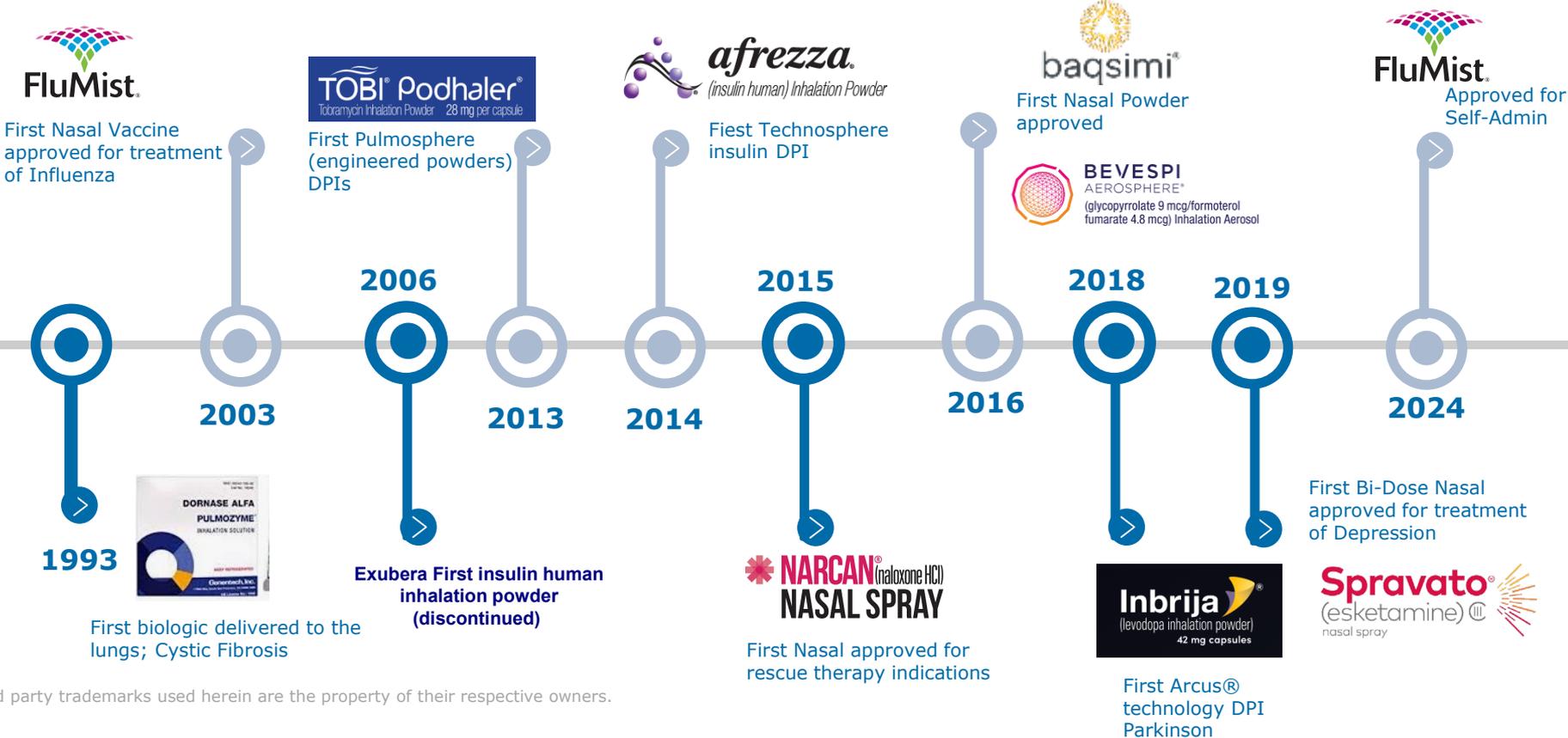


Source: PharmaProjects, Internal Analysis

## Key Insights

- **Neurological diseases** drive small molecule nasal pipeline growth (addiction, pain, migraine, depression)
- **Anti-infectives** growth Covid related (prophylaxis)
- **Anti-infectives, Vaccines, immunostimulants** driver of the large molecule nasal pipeline growth
- **Unit dose delivery** predominant in vaccines, immunostimulants

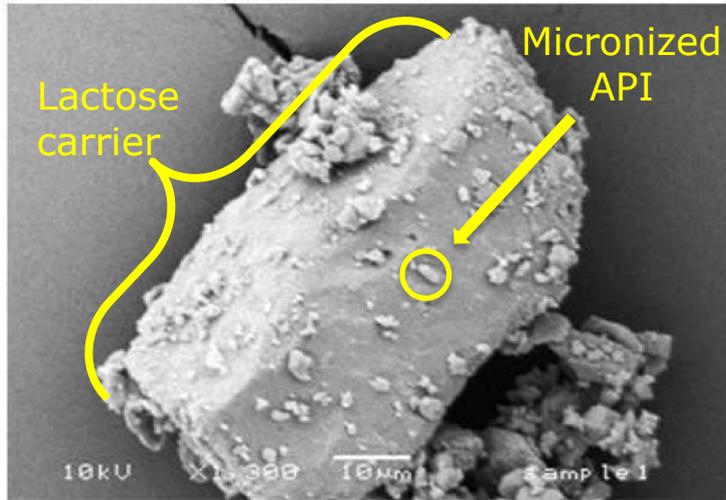
# Disruptive OINDPs technologies – timeline of FDA approvals



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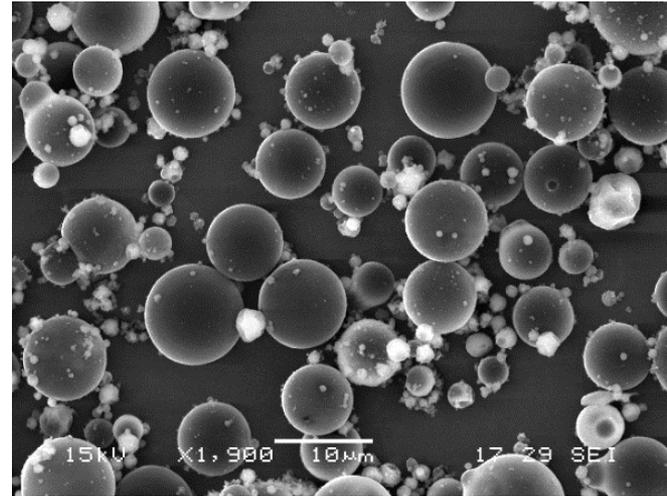
# DPI Formulation Approaches

## Coarse Carrier Blends



**Top-down:** Micronized (jet-milled) powder blended with coarse lactose carrier

## Spray-dried Powder



**Bottom-up:** Feed-stock (typically solution) atomized in drying chamber to engineer particles

# New delivery platforms in Inhalation & Nasal

## Approved spray-dried powders

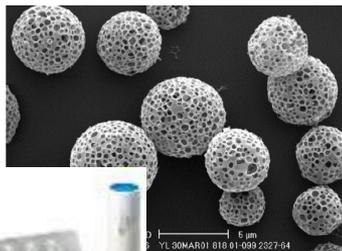
### pMDI



Porous  
Spray  
dried non-  
detaching  
carrier  
particle



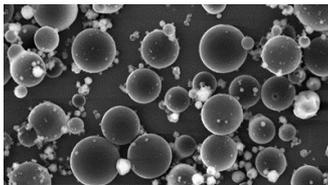
### Dry Powder Inhalation



Porous spray-  
dried drug-  
imbedded  
particle



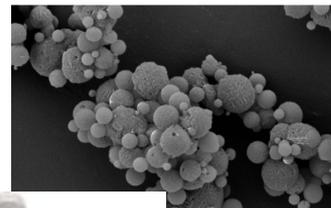
**TOBI Podhaler**  
Tobramycin Inhalation Powder 28 mg per capsule



Spray-dried,  
drug-  
imbedded  
hollow  
spheres



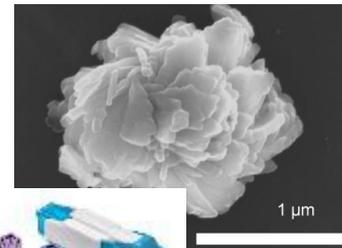
**Inbrija**  
(levodopa inhalation powder)  
42 mg capsules



Neat (100%  
API) spray-  
dried particle



**Bronchitol**  
(mannitol) inhalation powder



API surface  
coated  
particles  
produced  
by spray  
drying



**TYVASO DPI**  
(treprostinil) INHALATION  
POWDER

Public literature images

E.g. Pharmaceutical Particle Engineering via Spray Drying; Pharmaceutical Research, Vol. 25, No. 5, May 2008

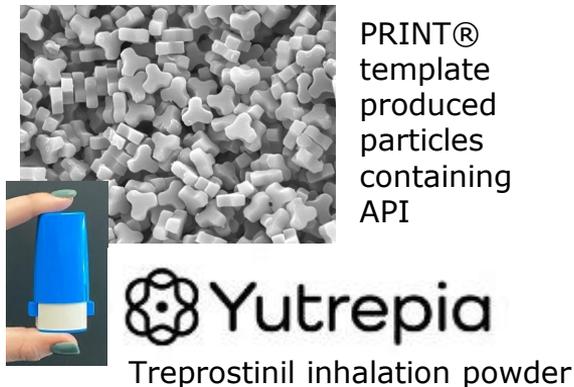
Pharmaceutical Particle Engineering via Nano Spray Drying - Process Parameters and Application Examples on the Laboratory-Scale

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# New powder delivery platforms in Inhalation & Nasal

## Non-spray-dried powder products

### Oral Inhalation



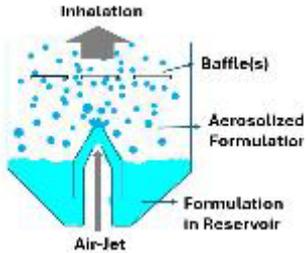
### Nasal



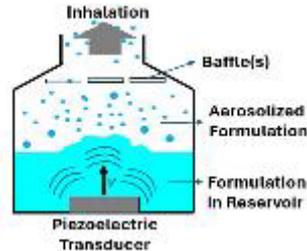
# Advances in device systems – challenging “sameness”

## Aqueous aerosol product mechanisms

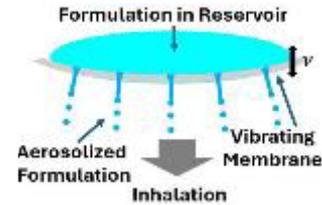
### Air-Jet



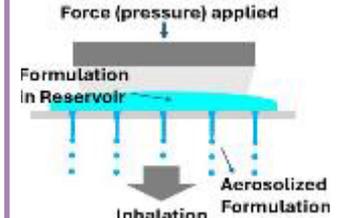
### Ultrasonic



### Vibrating Mesh



### Soft Mist



Images:

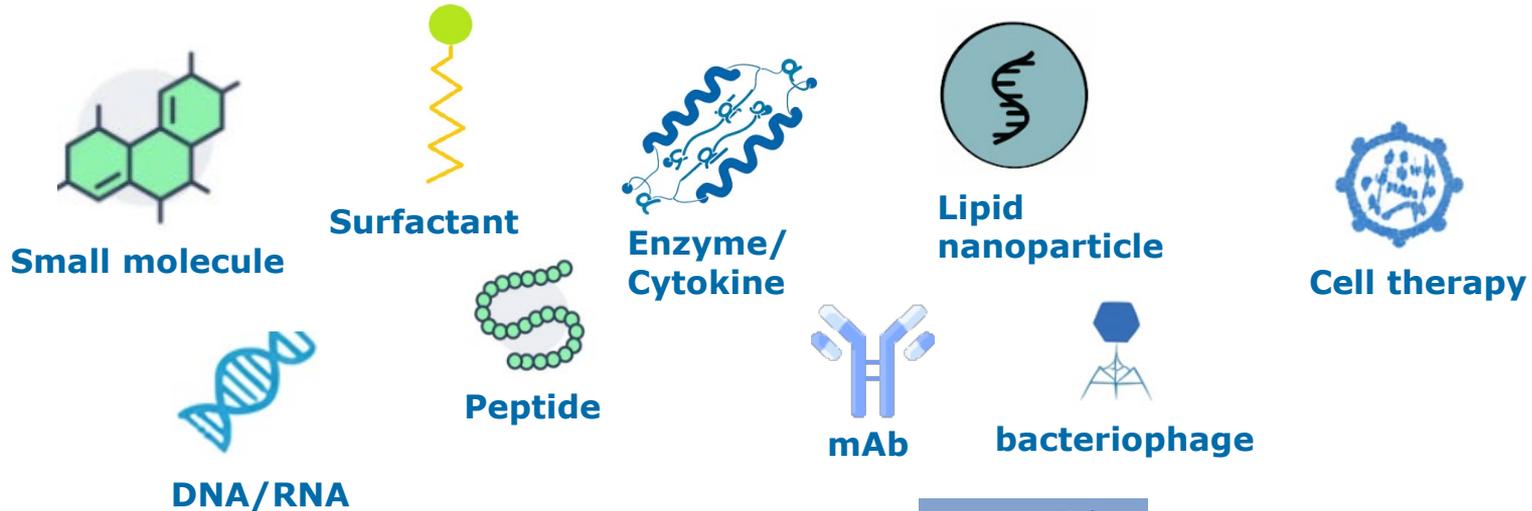
Air jet - [How to Use a Nebulizer - Allergy & Asthma Network](#)

Ultrasonic - [Benefits of Home Nursing Visits for Nebulization - Zorgers Blog](#)

Vibrating mesh - [eFlow@rapid Nebuliser System with eBase@ Controller - PARI](#)

Smi - [Soft Mist Inhalers Market Worth USD 4.4 Bn, Growing at 6.8% CAGR](#)

# Future Multi-therapeutic modalities will require CDER/CBER/CDRH coordination



nanoparticles

Nucleic acids

Proteins

Virus/bacteria

Biologics

< 900 Dalton - CDER

> 900 Dalton - CBER

## Future GDUFA research recommendations for complex generics delivered by the pulmonary and nasal route

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- Q1/Q2 demonstration for inactive ingredients required in PSGs – research needed to support alternative inactive ingredient options for generics of powders for lung and nasal delivery
- Qualification of new excipients to be permitted in inhalation and nasal generics
- Upgrade and flexibilize the concept of device sameness based on new device technologies and provide range of alternatives for generics
- Cooperation with CBER to introduce biosimilar concepts for inhalation and nasal products
- Understand underlying mechanisms for immunogenicity caused by pulmonary protein delivery to set appropriate level of controls for generics

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