



# EXELA

PHARMA SCIENCES



# Presentation Overview

- I. Pharmaceutical Industry, Facts, Figures and Uniqueness
- II. Overall Economic Impact
- III. Generic Pharmaceuticals – Essential to Health Care
- IV. Pharma Manufacturing in the US - Strategic Significance
  - Excessive Importation
- V. Exela Pharma Sciences – Overview
  - Virtual Facilities Tour
  - 2018 Expansion
  - Recognitions
  - Deep Gratitude



# PHARMACEUTICAL INDUSTRY – FACTS, FIGURES AND UNIQUENESS

# Pharmaceutical Industry Overview

## Facts, Figures and Uniqueness

Highly regulated - by the FDA

### Entry Barrier

- ❖ Upfront intensive investment. (Minimum **\$20-40M**)
- ❖ Facilities and processes need to be established and approved by the FDA before product enters the market – 5 yrs before returns

### Operational Inflexibility

- ❖ Inefficiencies in manufacturing (about 50%, *cf* to 70-80% at peers)
- ❖ Opportunities in market place: great flexibility/ huge expenditures

# Industry Facts, Figures and Uniqueness

## Working Capital

(Pharma Underperforms)

## Finished Goods

Average pharmaco holds 180 days of finished goods inventory on hand  
Consumer goods industry holds only 60 days' inventory

## Raw Materials

Now-a-days, it is about **8-12 months**.

Suppliers shifted the risk and inventory costs on drug manufacturers  
Practically all inputs are made to order

## Quality Costs (High)

25-30% of conversion costs are for quality standards

## Benchmarking

### INDIA

- ❖ Prices are 85 to 90% lower than in the US.  
E.g.: Tablets cost \$2/1,000. Roughly \$60 for the same in US.
- ❖ Establishing an FDA-inspected plant in India costs about 50% less than in the US.
- ❖ Operation and production costs run 40 to 70% lower.
- ❖ Labor costs are 60 to 70% less than in the US.



# OVERALL ECONOMIC IMPACT

# Biopharma Industry Overview

## Employment

About 854,000 employees in the US in 2014

Employment Multiplier = 5.21.

Supported approximately 3.6 million additional U.S. jobs.

Average annual wages and benefits: More than \$123,000 –  
more than twice the U.S. average across all industries

Biopharmaceutical industry jobs are both high-wage and high-quality.

## Economic Output

More than \$1.2 trillion  
represents 3.8 percent of the total U.S. output in 2014.

(Source: BIO)





# GENERIC PHARMACEUTICALS - ESSENTIAL TO HEALTH CARE

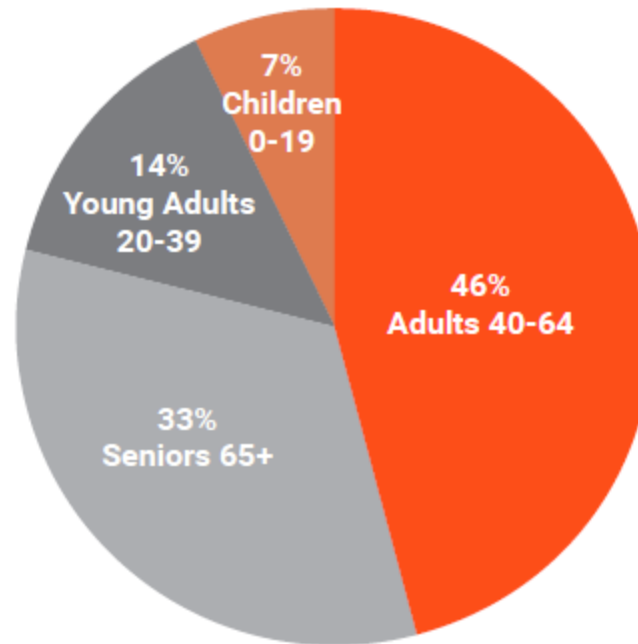
# Industry Facts, Figures and Uniqueness

## Total U.S. Healthcare Spending



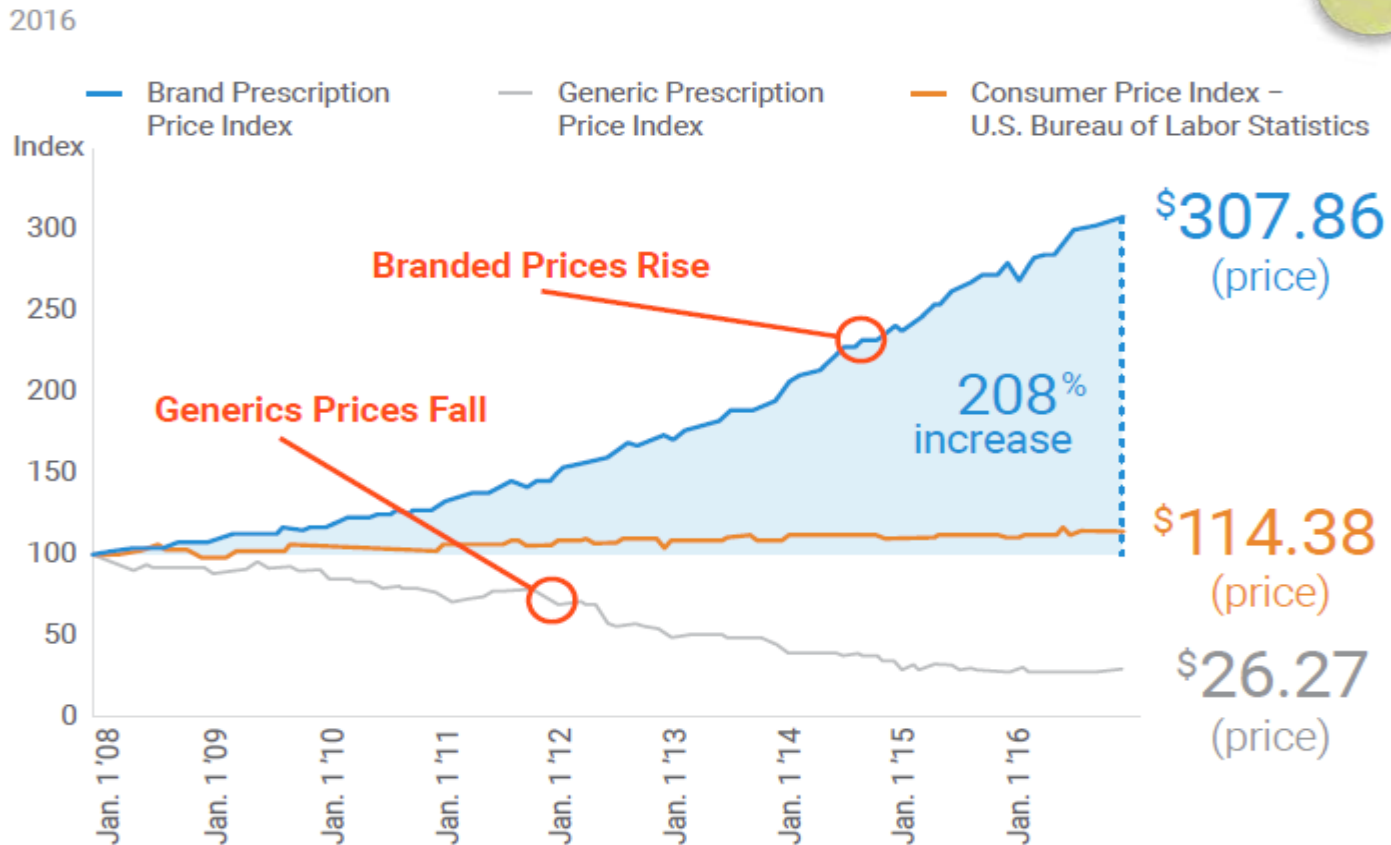
# Industry Facts, Figures and Uniqueness

2016 Generic Savings by Patient Age (%)



# Industry Facts, Figures and Uniqueness

## Express Scripts Prescription Price Index



# Industry Facts, Figures and Uniqueness

Nearly 3.9 Billion Generic Prescriptions  
were Dispensed in 2016

**89%**  **26%**

Generics account for 89% of prescriptions dispensed but only 26% of total drug costs in the US.

## Brand Drugs Drive Costs

Brands account for only

**11%**

of prescriptions  
(500 million)



yet are

**74%**

of the cost.  
(\$333.9 billion)

# Industry Facts, Figures and Uniqueness

2016 Savings **\$253** Billion

10-Year Savings **\$1.67** Trillion

Generic medicines generated \$253 billion in savings in 2016. One-quarter of a trillion dollars.

The U.S. healthcare system has saved \$1.67 trillion in the last decade due to the availability of low-cost generics.



# PHARMA MANUFACTURING IN THE US - STRATEGIC SIGNIFICANCE

# Manufacturing Generally

- ❖ The vast majority of manufacturing firms in the United States are quite small.
- ❖ In 2015, there were 251,774 firms in the manufacturing sector, with all but 3,813 firms considered to be small (i.e., having fewer than 500 employees).
- ❖ Three-quarters of these firms have fewer than 20 employees.

(Source: U.S. Census Bureau, Statistics of U.S. Businesses)



## Manufacturing Exports

Over the past 25 years, U.S.-manufactured goods exports have quadrupled.

- ❖ In 1990 - \$329.5B.
- ❖ In 2014 - \$1.403 trillion.

## Trade Surplus/Deficit in 2015

- ❖ \$12.7B surplus with its trade agreement partners
- ❖ \$639.6 billion deficit with other countries.

(Source: U.S. Commerce Department)



# EXCESSIVE IMPORTATION

# Overdependence on China and India

India and China supply about 60-80% of the US drug products

India and China supply about 70-85% of the US bulk drug (API) requirements

India and China combined have over 1600 API manufacturing facilities

India imports 92% of its raw materials that go into its API and drug product manufacturing from China (about \$6B).

Chinese API/raw materials are four times cheaper than Indian APIs

Recent border tensions between India and China led to the following:

The Commerce Minister said: “the government was fully seized of the issue of the country's dependence on import of APIs and that inbound shipments "are coming from a particular country and as a result, (there are) national security concerns".

Read more at:

[//economictimes.indiatimes.com/articleshow/57790774.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](http://economictimes.indiatimes.com/articleshow/57790774.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)

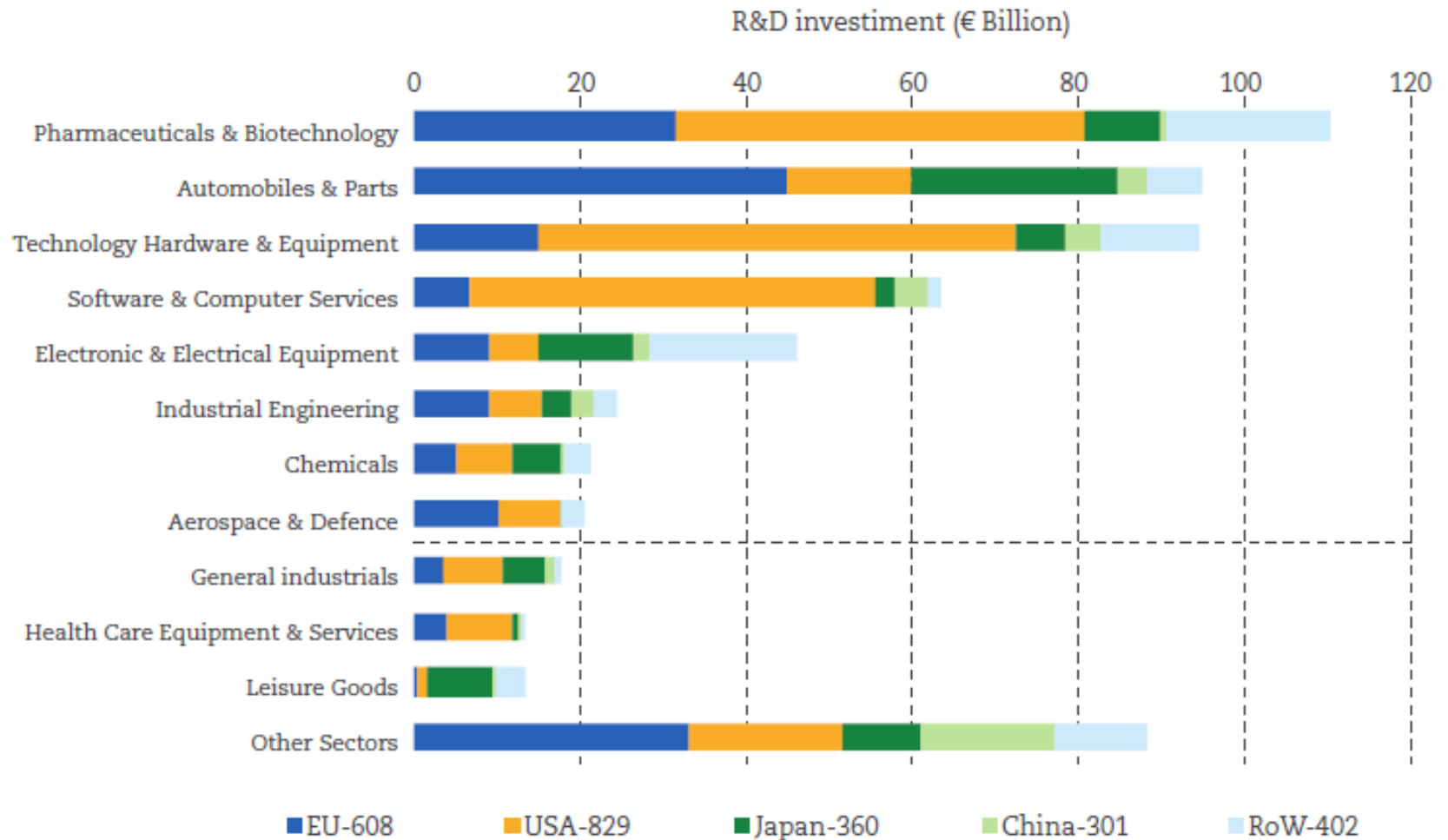
**This overdependence is and should be a strategic concern for us in the US as well.**

## Our current status

- a) Drug shortages are a serious concern; have been happening since 2008. Still no process to get drug products made/released efficiently.
- b) FDA and others cannot turn quickly to address the matters or open to creative solutions
- c) The only quick solution today is importation from another country.

**We cannot afford to be depleted of manufacturing capability in the US**

# R&D Investments



## Key Take Away

**Our R&D is the highest in the world**

**Our manufacturing is disproportional as reflected  
by drug product imports**

**A Major Strategic Issue**



# EXELA OVERVIEW

# Who is EXELA Pharma Sciences?

**“Developer and Manufacturer of sterile products with the healthcare provider and patient in mind”**

## Key Highlights

- Headquartered in Lenoir, North Carolina
- All development and manufacturing is in the US
- Founded in 2005 - privately held
- Over 275 employees and growing, 30% in Quality functions
- 20,000sf manufacturing space, liquid vials, Lyo vials, IV Bags, ophthalmics
- 80,000sf expansion underway to add 6 new sterile suites and Pre-Filled Syringe capability
- Good cGMP track record with USFDA inspections (2012, 2013, 2014, 2016 & 2017)
- Currently manufacture and market 20 FDA approved sterile injectable drugs, plus 3 injectable drugs in Canada (Health Canada approved)
- Fifteen products filed and pending at FDA, 30+ products in the pipeline
- Focused on differentiated product development, primarily in sterile injectable



# EXELA's Economic Impact on Lenoir/Caldwell County

275 high paying manufacturing jobs

**Exela Average Salary: \$58,000**

**Caldwell County Average; \$33,000**

Diversification and transformation from furniture to world class state-of-the-art Pharmaceutical Manufacturing.



Full Impact: Employment Multiplier of 5 = 1375  
Full Impact: 1375 + 275 = **1,650 Jobs**

# What makes EXELA Pharma Sciences different?

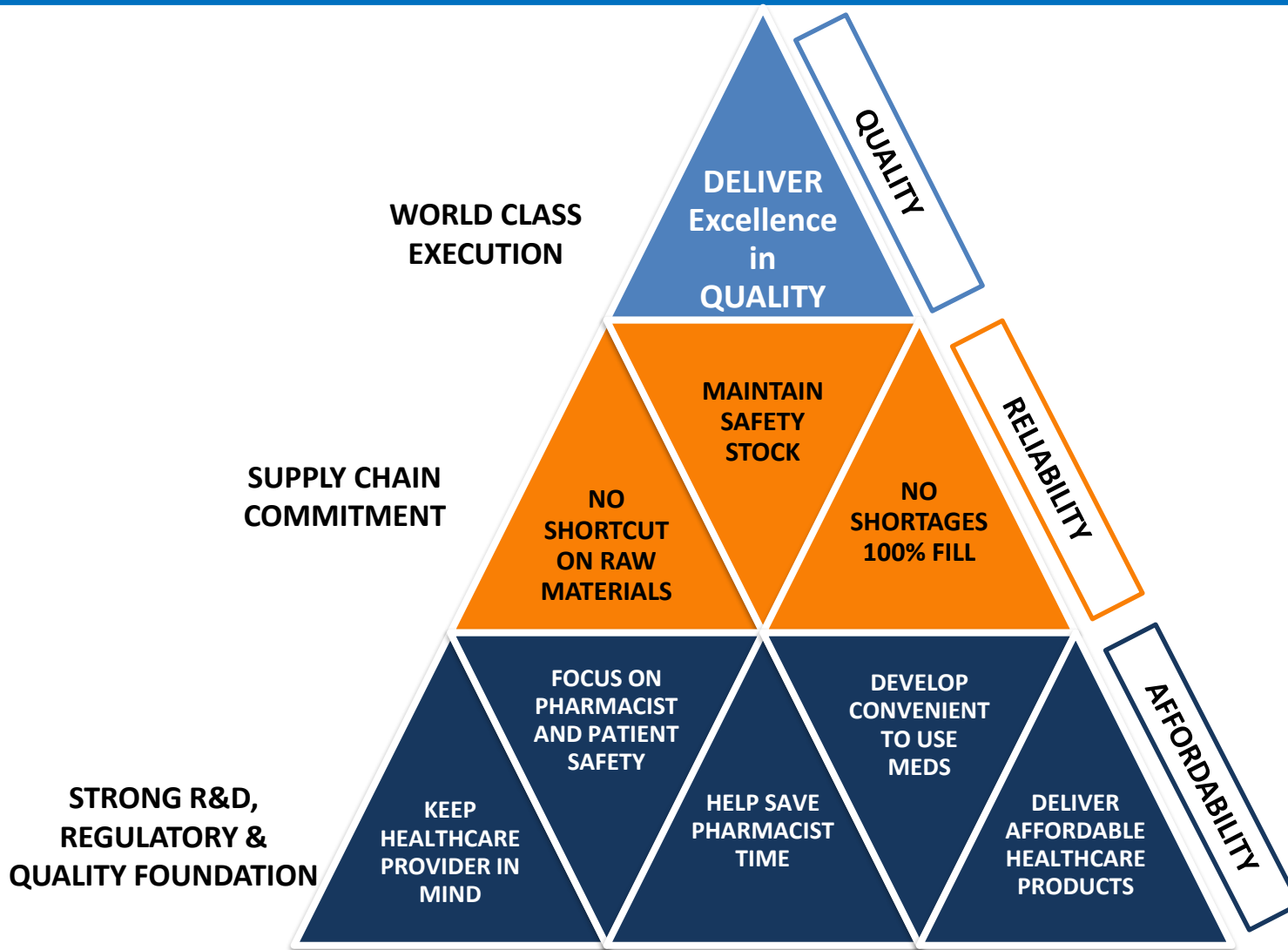
## Mission:

**“We believe that providing medicines to alleviate human pain and suffering is one of the noblest undertakings. Making medicines affordable and expediting their availability to the needy is a worthy goal. That is EXELA’s focus.”**

## Our Philosophy

- **Value Add in some way to each Product we manufacture without price gouging**

# Unwavering Commitment to End-User



SAFE > PURE > EFFECTIVE

# Overview of Facilities, Capabilities and Quality Systems

## Facility Overview

20,000 sf manufacturing space (vials and bags)

80,000 sf new manufacturing space under construction (vials, bags, pre-filled syringes)

145,000 sf Corporate, R&D, Quality, Packaging, Warehouse and Distribution Center

165,000 sf future expansion

## Manufacturing Capabilities

**Current** capability - Liquid and Lyo vials (10 mn vials/yr)

## **Future**

IV Bags – High speed bag filler being installed - (5 mn bags/yr)

Pre-Filled Syringes – High speed PFS machine being installed (40 mn/yr)

High Speed Vial Fillers – 2 lines being installed (40 mn vials/yr)

**TOTAL by 2019:** About 100 mn units/year

**Will be in the top 20 sterile small molecule manufacturing facilities in the US**

## Quality Systems

Very Good cGMP track record - FDA inspections (2012, 2013, 2014, 2016 & 2017)

# Commercialized Sterile Products

## EXELA Label Products

- Caffeine Citrate Injection - #2 Market Share
- Caffeine Citrate Oral Solution - #1 Market Share
- Potassium Acetate Injection - #2 Market Share
- Verapamil HCl injection - #2 Market Share
- NIPRIDE RTU (sodium nitroprusside) Injection
- GANZYK-RTU (ganciclovir injection) Ready to Use



## Partnered Products

- Nicardipine HCL Injection Vials – (WestWard) **(1<sup>st</sup> APPROVAL; P-IV) (b)(2)**
- Argatroban Injection Vials – (WestWard) **(1<sup>st</sup> APPROVAL; P-IV) (b)(2)**
- Paricalcitol Injection – (Westward) **(2<sup>nd</sup> GENERIC; P-IV) (b)(2)**
- Clonidine Hydrochloride Injection – (X-Gen) **(MAJOR SOURCE; Drug Shortage)**
- Magnesium Sulfate Injection – (X-Gen) **(DRUG SHORTAGE PRODUCT)**

## Contract Manufactured Products

- Streptomycin Injection – (X-Gen/US and Sterimax/Canada)
- Tranexamic Acid Injection – (X-Gen/US and Sterimax/Canada)
- Hydralazine Injection – (X-Gen/US and Sterimax/Canada)
- LEUTEchniLite Injection – (Lantheus)

# NIPRIDE RTU (Sodium Nitroprusside) Ready to Use Vials

**Launched March 2017**

- The **ONLY** ready-to-use sodium nitroprusside available.
- 0.5mg/mL (50mg /100mL) pre-diluted with normal saline.
- **Previous Product**
- Product was sold for **over 40 years** as a concentrated 2 mL vial that must be diluted in the hospital and protected from light with a shroud, and discarded if not used within 24 hrs
- **Our product** is stable for 24 months – no need to mix in the hospital; no need to use a shroud



# GANZYK-RTU – Ganciclovir Injection Bags

**Launched September 2017**

- The **ONLY** ready-to-use ganciclovir injection available.
- 500mg of ganciclovir in a pre-mixed 250mL bag.
- **Previous Product**
  - Must be diluted in the hospital
  - Has a very pH of about 11.0, which can cause reaction at the site of injection
  - Must take extra precautions to protect personnel from exposure during dilution activities
- **Our Product**
  - Already diluted
  - pH of about 7.5, same as our blood pH
  - no need to protect personnel
  - reduces potential medication errors
  - 24 months shelf life





# VIRTUAL FACILITIES TOUR

SAFE > PURE > EFFECTIVE

**EXELA**  
PHARMA SCIENCES



# Current Sites – Lenoir, North Carolina



# Current Facilities - Laboratory



**Formulations Laboratory**



**Gas Chromatographs and Atomic Absorption Spectrometer**



**HPLC Wall**



**Part of QA/QC Laboratory**

# Current Facilities - Manufacturing



**Vial Filler in Class 1000 suite  
with Class 100 RAB**



**Ophthalmic Filler in Class 1000 suite  
with Class 100 RAB**



**Class 1000 Corridor to Lyo Suite with  
State-of-the art particle monitoring system**



**Lyophilizer in Class 100 Suite**

# Current Facilities – Labeling & Inspection



Kalish Labeler with Vision System & Barcode Reader (70 vials/minute)



Manual Inspection Station

**EXELA performs 100% inspection to ensure product quality and integrity**

# Current Facilities – Labeling & Inspection



IMA Libra High Speed Labeler  
(400 vials/minute)



Seidenader High Speed Inspection Machine  
(400 vials/minute) (being validated)

**EXELA is building for the future with  
high speed automation**

# Current Facilities – Water System & Warehouse



WFI High Capacity Water System and Clean Steam Generator



Fully Validated **cGMP** Warehouse



## 2018 EXPANSION

# Exela Expansion - \$25-30M



Preparing to create Clean Rooms



Boiler Room



Water for Injection Equipment



Water for Injection Room





# RECOGNITIONS

# Exela Recognitions

- 2015

Industry of the Year, Caldwell County

- 2016

Horizons Award by Premier Inc.,

Second Largest Hospital Group Purchasing Organization in the US  
for best Supply Chain Performance by a rising Pharma Company

- 2017

Manufacturing Leadership Award - Developing Markets

Awarded by North Carolina Manufacturing Extension Partnership  
Presented by Honorable Governor Roy Cooper



# DEEP GRATITUDE

# Deep Gratitude . . .

- All of Exela's Employees and their Families
- Caldwell County, Economic Development Commission, Lenoir, NC, Deborah Murray
- City of Lenoir, NC
- Blue Ridge Electric Company, Lenoir, NC, Douglas Johnson
- North Carolina Rural Development Center, Raleigh, NC
- North Carolina State Economic Incentives Programs, Raleigh, NC
- US Small Business Administration
- US Department of Agriculture, Bruce Pleasant
- Community Bankshares, Inc., LaGrange, GA, William Stump, Jr.
- Metro City Bank, Atlanta, GA, Nack Paek
- Touchmark National Bank, Alpharetta, GA, Trae Dorough
- Thomas USAF, Atlanta, GA, Mike Thomas and Kathy Morris
- Deerfield Management Company, New York



# Thank You



***EXELArate* with us!**

**SAFE > PURE > EFFECTIVE**

**EXELA**  
PHARMA SCIENCES